

SITE CONDITION REPORT

Concept Life Sciences Integrated Discovery & Development Services
Limited – Environmental Permit Application



CONCEPT LIFE SCIENCES

JER8343
Site Condition Report
2
2
18 March 2020

Quality Management

| Version | Revision | Authored by | Reviewed by | Approved by | Date |
|---------|----------|---------------|-----------------------|-------------------|------------------|
| 1 | 0 | Tim Colebrook | n/a | n/a | 4 December 2019 |
| 1 | 1 | Tim Colebrook | Jennifer Stringer | Jennifer Stringer | 21 January 2020 |
| 2 | 0 | Tim Colebrook | Concept Life Sciences | n/a | 04 February 2020 |
| 2 | 1 | Tim Colebrook | Jennifer Stringer | Jennifer Stringer | 04 March 2020 |
| 2 | 2 | Tim Colebrook | Concept Life Sciences | n/a | 18 March 2020 |
| 2 | 3 | Tim Colebrook | Jennifer Stringer | Jennifer Stringer | 23 March 2020 |

Approval for issue

Jennifer Stringer

Technical Director



23 March 2020

File Name

200323_R_JER8343_TC_Site Condition Report_V2_R3.docx

© Copyright RPS Group Plc. All rights reserved.

The report has been prepared for the exclusive use of our client and unless otherwise agreed in writing by RPS Group Plc, any of its subsidiaries, or a related entity (collectively 'RPS'), no other party may use, make use of, or rely on the contents of this report. The report has been compiled using the resources agreed with the client and in accordance with the scope of work agreed with the client. No liability is accepted by RPS for any use of this report, other than the purpose for which it was prepared. The report does not account for any changes relating to the subject matter of the report, or any legislative or regulatory changes that have occurred since the report was produced and that may affect the report. RPS does not accept any responsibility or liability for loss whatsoever to any third party caused by, related to or arising out of any use or reliance on the report.

RPS accepts no responsibility for any documents or information supplied to RPS by others and no legal liability arising from the use by others of opinions or data contained in this report. It is expressly stated that no independent verification of any documents or information supplied by others has been made. RPS has used reasonable skill, care and diligence in compiling this report and no warranty is provided as to the report's accuracy. No part of this report may be copied or reproduced, by any means, without the prior written consent of RPS.

Prepared by:

RPS

Tim Colebrook

Senior Consultant

260 Park Avenue

Almondsbury

Bristol

BS32 4SY

T +44 1454 853 000

E tim.colebrook@rpsgroup.com

Prepared for:

Concept Life Sciences

Contents

| | | |
|----------|--|-----------|
| 1 | INTRODUCTION | 1 |
| 1.1 | Background | 1 |
| 1.2 | Key Objectives | 1 |
| 1.3 | Report Structure | 3 |
| 2 | APPLICATION SITE CONDITION REPORT | 4 |
| 2.1 | Description of Permitted Activities | 4 |
| 2.2 | Application Phase | 4 |
| 2.3 | Site Condition Report Summary..... | 5 |
| 3 | STAGE 1 - IDENTIFY WHICH HAZARDOUS SUBSTANCES ARE USED, PRODUCED OR RELEASED AT THE INSTALLATION AND PRODUCE A LIST OF THESE SUBSTANCES | 7 |
| 4 | STAGE 2 – IDENTIFYING THE RELEVANT HAZARDOUS SUBSTANCES’ | 17 |
| 5 | STAGE 3 – ASSESSMENT OF THE SITE-SPECIFIC POLLUTION POSSIBILITY | 19 |
| 5.1 | Site-Specific Pollution Possibility | 19 |
| 5.2 | Risk Matrix for Determining Site-Specific Pollution Potential..... | 19 |
| | Likelihood of Accidental Release / Emission Occurring | 19 |
| | Likelihood of Receptor being Affected | 20 |
| 5.3 | Site Location..... | 21 |
| 5.4 | Proposed Operations and Layout | 21 |
| | Surface Water Drainage System..... | 24 |
| | Potential Release Scenarios | 24 |
| | Pathways and Associated Pollution Prevention Measures | 24 |
| | Product handling and storage | 25 |
| | Minimisation of environmental impact | 25 |
| | Ground protection | 26 |
| | Enclosure of sources..... | 26 |
| | Assessment of Site-specific Pollution Risk | 34 |
| 6 | STAGE 4 – PROVIDE A SITE HISTORY | 38 |
| 6.1 | Introduction..... | 38 |
| 6.2 | General Site History | 38 |
| | Current Land Use | 38 |
| | Historical Land-use | 38 |
| 6.3 | Surrounding Land-use..... | 39 |
| | Current Overview | 39 |
| 6.4 | Pollution History | 39 |
| | Pollution Incidents | 39 |
| 6.5 | Potential for the Release of Hazardous Substances | 40 |
| 6.6 | Previous Ground Investigation | 40 |
| | Ground Conditions | 40 |
| | Baseline Soil and Groundwater Data | 40 |
| 6.7 | Potential Historic Contaminants | 40 |
| | Soil Data Summary | 41 |
| | Groundwater Data Summary | 41 |
| 6.8 | Operational History | 42 |
| 7 | STAGE 5 – IDENTIFY THE SITE’S ENVIRONMENTAL SETTING | 43 |
| 7.1 | Introduction..... | 43 |
| 7.2 | Site Setting and Sources of Desk Study Information | 43 |
| 7.3 | Topography | 43 |
| 7.4 | Geology | 43 |
| 7.5 | Hydrogeology | 44 |
| 7.6 | Hydrology | 44 |
| 7.7 | Man-made Pathways | 44 |

| | | |
|-----------|---|-----------|
| 7.8 | Environmental Consents, Licenses, Authorisations, Permits and Designations for the Site and Surrounding Areas | 44 |
| | Water Discharges and Abstraction Licenses | 44 |
| | Landfill Sites | 47 |
| | Permitted Sites | 47 |
| | Statutory Designated Sites within 10km | 51 |
| | Mining 51 | |
| | COMAH and Hazardous Substance Consents | 51 |
| | Radon 52 | |
| 8 | STAGE 6 – SITE CHARACTERISATION | 53 |
| 8.1 | Introduction..... | 53 |
| 8.2 | Potential Contamination Sources..... | 53 |
| 8.3 | Identified Receptors | 53 |
| 8.4 | Pathways..... | 53 |
| 9 | STAGE 7 – SITE INVESTIGATION | 56 |
| 10 | STAGE 8 – PRODUCE A BASELINE REPORT | 59 |
| 10.1 | Introduction..... | 59 |
| 10.2 | Baseline Soil Quality | 59 |
| 10.3 | Baseline Groundwater Quality | 65 |
| 10.4 | Baseline Gas Assessment | 66 |
| 10.5 | Ground Conditions | 66 |
| 10.6 | Field Observations of Contamination | 66 |
| 11 | OPERATIONAL PHASE SITE CONDITION REPORT | 67 |
| 11.1 | Operational Phase | 67 |
| 11.2 | Site Condition Report Summary..... | 67 |
| 12 | SURRENDER SITE CONDITION REPORT | 68 |
| 13 | CONCLUSIONS | 69 |
| | GLOSSARY..... | 71 |
| | REFERENCES | 73 |

Tables

| | | |
|-------------|---|----|
| Table 3.1 | Materials Inventory | 8 |
| Table 3.2 | Hazardous Materials Inventory | 10 |
| Table 5.1: | Risk Matrix for Determining Site-Specific Pollution Potential | 20 |
| Table 5.2 | Description of Activities | 22 |
| Table 5.3 | Bund Details | 33 |
| Table 5.4: | Assessment of Site-Specific Pollution Potential | 35 |
| Table 6.1: | Summary of Registered Permitted Sites | 39 |
| Table 7.1: | Discharge Consents | 45 |
| Table 7.2: | Water abstractions..... | 46 |
| Table 7.3: | Summary of registered historical and active landfill sites..... | 47 |
| Table 7.4: | Summary of Registered Permitted Sites | 48 |
| Table 7.5: | Statutory Designated Sites | 51 |
| Table 7.6: | COMAH and Hazardous Substance Consents | 51 |
| Table 7.7: | Planning Hazardous Substance Consents..... | 51 |
| Table 8.1: | Conceptual Site Model – Human Health Receptors..... | 55 |
| Table 8.2: | Conceptual Site Model – Controlled Water Receptor..... | 55 |
| Table 9.1: | Summary of Borehole Depths and Well Installation Details..... | 57 |
| Table 9.2: | Geological Summary | 57 |
| Table 9.3: | Summary of Groundwater Levels | 58 |
| Table 10.1: | Summary of Soil Analytical Results (Boreholes PP_BH2 & PP_BH3)..... | 60 |

Figures

| | |
|---|----|
| Figure 5-1: Raw Materials Flow | 27 |
| Figure 5-2: Raw Materials Storage | 28 |
| Figure 5-3: Internal Storage Area | 29 |
| Figure 5-4: Breakdown of anticipated storage utilisation and bund arrangement | 30 |
| Figure 5-5: External Storage Areas and Bunds..... | 31 |
| Figure 5-6: Breakdown of Internal Bund Locations and Volumes | 32 |

Appendices

| |
|---|
| Appendix A Site Plans |
| Appendix B URS Baseline Soil and Groundwater Investigation, June 2014 |
| Appendix C Landmark Envirocheck Report |
| Appendix D Safety Data Sheets |
| Appendix E Pfizer Building 901 Decommissioning Report |
| Appendix F Environment Agency Nature and Heritage Conservation Screening Report |

1 INTRODUCTION

1.1 Background

1.1.1 Concept Life Sciences Integrated Discovery & Development Services Limited (CLS) Sandwich currently operate a research and development laboratory for small scale clinical trial active pharmaceutical ingredient (API) manufacture to 2 kg batch sizes. As part of an expansion projects, CLS are now looking to develop a commercial production facility to produce larger scale API's and have acquired, as a tenant, a separate facility (Building 901) to enable manufacture of clinical trial API materials to 5 kg batch sizes.

The proposed activity to be undertaken in Building 901 by CLS falls under the Environmental Permitting (England and Wales) Regulations 2016 as follows:

SECTION 4.5 Pharmaceutical Production

Part A(1)(a) Producing pharmaceutical products.

1.1.2 In addition, the following directly associated activities (DAAs) are carried out at the site:

- Storage and handling of raw materials and chemicals; and
- Chiller units providing cooling using glycol.

1.1.3 As part of the application for an environmental permit, operators are required to submit an application site condition (ASC) and Industrial Emissions Directive (IED) baseline report to inform the Environment Agency (EA) of the setting of the condition of the land and groundwater at the application stage 'initial condition' and the Relevant Hazardous Substances (RHS) that will be present on site prior to the operational activities commencing. This report will be updated upon cessation of activities to establish if contamination of land has occurred during site occupancy and whether or not remediation will be required at permit surrender.

1.1.4 Site plans can be found in Appendix A.

1.1.5 For the purposes of this application it has previously been agreed with the EA that a Baseline Soil and Groundwater Investigation (URS, June 2014) produced to inform the Site Condition Report for a Variation Application to environmental permit reference CP3339LY for Pfizer Limited, Sandwich in June 2014 (Ref: 47070578 / LORP0002) can be used to provide relevant information due to the proximity of the Pfizer installation. A copy of the URS Baseline Soil and Groundwater Investigation report is included as Appendix B to this report.

1.1.6 This document comprises the ASC and IED baseline report, it establishes the condition of the land within the permit boundary at the point of application for an environmental permit and is informed by a Landmark Envirocheck Report and a URS Baseline Soil and Groundwater Investigation (June 2014).

1.2 Key Objectives

1.2.1 This site condition report (SCR) describes and records the condition of the land and groundwater at a site at particular points in time. It shall be updated during the lifetime of the permit as appropriate and upon application to surrender the permit, the condition of the land and groundwater shall be assessed to demonstrate that they are in a satisfactory condition to surrender the environmental permit.

1.2.2 The content and approach for delivery of a Baseline Report is described in European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions (2014/C136/03), dated 6 May 2014 ("Communication 2014/C136/03").

-
- 1.2.3 A number of key tasks should be undertaken to both determine whether a baseline report needs to be produced for a particular situation and in order to produce the baseline report itself. Eight stages have been identified in this process, covering the following main elements:
- Stages 1-3: to decide whether a baseline report is required;
 - Stages 4-7: to determine how a baseline report has to be prepared;
 - Stage 8: to determine the content of the report.
- 1.2.4 Where during stages 1-3 it is demonstrated on the basis of the available information that a baseline report is not required, there is no need to progress to the later stages. A record of such a demonstration should be made and held by the competent authority, including the reasons for such a decision.
- 1.2.5 The objective of this report is to deliver the eight-stage approach described in Communication 2014/C136/03 that includes:
- Stage 1 – Identify hazardous substances used, produced or released at the installation;
 - Stage 2 – Identify those substances which are relevant hazardous substances, or which represent a theoretical pollution risk;
 - Stage 3 – Undertake an assessment of site-specific pollution risk for relevant hazardous substances;
 - Stage 4 – Evaluation of site history and potential for relevant hazardous substances to be present in soils and groundwater as a result of historic activities;
 - Stage 5 – Evaluation of environmental setting to determine the fate of potential emissions of relevant hazardous substances;
 - Stage 6 – Site characterisation;
 - Stage 7 – Need for further site investigation;
 - Stage 8 – Produce a baseline assessment for the installation that quantifies the state of soil and groundwater pollution by relevant hazardous substances.
- 1.2.6 This SCR & IED Baseline Report includes the development of a Conceptual Site Model (CSM) and delivery of a site-specific assessment of pollution potential for the substances used, produced or emitted as part of the permitted operations at the proposed facility. The site-specific pollution potential is determined from a desk-based evaluation of the proposed operations and a qualitative assessment of the associated risk.
- 1.2.7 The evaluation of the possibility of contamination occurring in relation to RHS has been termed an assessment of “site-specific pollution potential”. A qualitative, desk based, approach has been used to determine site- specific pollution potential. This approach involves the following steps:
- Summary of all potentially hazardous substances used, produced, emitted on the proposed installation (Substance Inventory) and the associated processes, storage, use and handling thereof;
 - Determination of which substances constitute RHSs as defined by IED;
 - Identification of possible release scenarios and associated mitigation measures incorporated in to design and or operational measures (e.g. through Environmental Management Systems ((EMS)) developed for the facility;
 - Consideration of CSM to determine whether a plausible pollutant linkage exists that could connect the contamination source to soil or groundwater receptors; and
 - Assessment of site-specific pollution potential using a qualitative risk matrix approach.

1.3 Report Structure

1.3.1 The subsequent report structure is as follows:

- Section 2: Application Site Condition Report
- Section 3: IED Baseline Assessment Stage 1 - determine whether or not hazardous substances are used, produced or released in view of deciding on the need to prepare and submit a baseline report.
- Section 4: IED Baseline Assessment Stage 2 - identify the relevant hazardous substances from those identified in the stage 1 assessment.
- Section 5: IED Baseline Assessment Stage 3 - to identify which of the relevant hazardous substances represent a potential pollution risk at the site based on the likelihood of releases of such substances occurring. For these substances, information must be included in the baseline report.
- Section 6: IED Baseline Assessment Stage 4 - provide a site history to identify potential sources which may have resulted in the hazardous substances identified in Stage 3 being already present on the site of the installation.
- Section 7: IED Baseline Assessment Stage 5 - identify the site's environmental setting. Determine where hazardous substances may go if released and where to look for them. Also identify the environmental media and receptors that are potentially at risk and where there are other activities in the area which release the same hazardous substances and may cause them to migrate onto the site.
- Section 8: IED Baseline Assessment Stage 6 - characterise the site. Identify the location, nature and extent of existing pollution on the site and to determine which strata and groundwater might be affected by such pollution. Compare with potential future emissions to see if areas are coincident.
- Section 9: IED Baseline Assessment Stage 7 - carry out a site investigation to obtain additional information where only part of the site can be characterised or there is insufficient information on which to formulate a baseline report. Collect additional information as necessary to allow a quantified assessment of soil and groundwater pollution by relevant hazardous substances.
- Section 10: IED Baseline Assessment Stage 8 - Stage 8 of the IED baseline assessment is summarise all of the information collected in stages 1 to 7 to produce a report which identifies the state of the soil and groundwater contamination by relevant hazardous substances.
- Section 11: Operational Phase Site Condition Report
- Section 12: Surrender Site Condition Report
- Section 13: Conclusions

2 APPLICATION SITE CONDITION REPORT

2.1 Description of Permitted Activities

- 2.1.1 Building 901 comprises of a manufacturing area containing walk in fume hoods, a scrubber system, a sperate area for housing drying ovens, a materials storage area, office and welfare facilities. The upper floor houses the associated building infrastructure and equipment such as fume hood extraction fans, air handling units and power.
- 2.1.2 CLS plan to install and recommission six approximately 100 L vessels, two filter driers, two drying oven, two glovebox and associated small mobile equipment to enable the manufacture of active pharmaceutical ingredients (API) for clinical trials. The building will store the raw materials and packaging for the processes. An analytical laboratory and office area will be housed within the facility to support the activities.
- 2.1.3 The vessels will have thermoregulation capability through the use of mobile heat/cool units, condensers utilising water or glycol as chilling media for abatement and bottled nitrogen for vessel inertion.
- 2.1.4 The drying oven will utilise electric water heater, vacuum and nitrogen services.
- 2.1.5 Process waste such as solvents will be stored in suitably rated and chemically resistant containers prior to incineration.
- 2.1.6 The reactors will vent to atmosphere via condensers and a wet scrubber.
- 2.1.7 The operation is designed to run one manufacturing process in two vessels and full occupancy in 2020 should generate approximately six campaigns and 15 to 30kg of clinical trial API. The operation has the capability to increase by a further four vessels with associated drying and mobile equipment in 2021 with the production of up to 90kg of clinical API per annum. This will allow three manufacturing processes to be run concurrently in the six vessels.

2.2 Application Phase

- 2.2.1 This SCR has been prepared in accordance with the EA “H5 Site Condition Report” guidance¹ and in accordance with the European Commission Guidance² concerning baseline reports required under the IED, it contains information on the condition of the site from June 2014, when the URS Infrastructure & Environment UK Limited ground investigation was carried out to determine current baseline conditions of the site. The site history prior to 2014 has been reviewed where known and commented on within this report.
- 2.2.2 Key information regarding historical and current land use can be found in in the Landmark Envirocheck Report in Appendix C.
- 2.2.3 The site-specific pollution potential is dependent on the CSM developed on for the facility using the concept of Pollutant (Source-Pathway-Receptor) Linkages, which in turn is dependent on the conceptual hydrogeology and ground model of the system. An active Pollutant Linkage enables known or potential contamination sources to be linked with a specific environmental receptor via a plausible transport pathway.
- 2.2.4 The pollutant linkages defined for the CLS installation are therefore dependent on the nature of potential release scenarios associated with each RHS and the nature of any pollution prevention measures or mitigation measures implemented on the site (e.g. through facility design /

¹ <https://www.gov.uk/government/publications/environmental-permitting-h5-site-condition-report>

² [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52014XC0506\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52014XC0506(01)&from=EN)

engineering, nature of on-site containment, emergency response measures, routine inspection / maintenance protocols etc.).

2.3 Site Condition Report Summary

| 1.0 Site Details | |
|--|--|
| Name of the applicant | Concept Life Sciences Integrated Discovery & Development Services Limited |
| Activity address | Kilo Facility, Building 901, Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND |
| National grid reference | TR 33531 59617 |
| Site area (ha) | ~0.1 ha (~1,420 m ²) |
| Document reference and dates for Site Condition Report at permit application and surrender | Permit Application - 191204_R_JER8343_TC_Site Condition Report_V1_R0. January 2020 |
| Document references for site plans (including location and boundaries): | The following site plans are included in Appendix A: Site Plans_January 2020 Summary of building 901 drainage Summary of B901 internal and external storage areas 901-007-011-000-00001 Drainage Layout SAN-901-007-004-000-00001 Building Drainage Layout Ground Floor SAN-901-007-004-000-00002 Underground services SAN-901-007-004-010-00001 Building Drainage Layout First Floor |

| 2.0 Condition of the land at permit issue | |
|--|--|
| Environmental setting including: <ul style="list-style-type: none"> • Geology • Hydrogeology • Surface waters | Details of the environmental setting are provided in Section Error! Reference source not found. of this SCR and Baseline Report. |
| Pollution history including: <ul style="list-style-type: none"> • pollution incidents that may have affected land • historical land-uses and associated contaminants • any visual/olfactory evidence of existing contamination • evidence of damage to pollution prevention measures | Pollution history details are provided in section 6.4 of this SCR and Baseline Report. |
| Evidence of historic contamination, for example, historical site investigation, assessment, remediation and verification reports (where available) | Any details regarding historical contamination at the site are provided in Section 6.7 of this SCR and Baseline Report. |
| Baseline soil and groundwater reference data | Details regarding baseline soil and groundwater reference data at the site are provided in Section 6.7 of this SCR and Baseline Report. |
| Supporting information | <ul style="list-style-type: none"> • Appendix A – Site Plans • Appendix B – URS Baseline Soil and Groundwater Investigation (June 2014) • Appendix C – Envirocheck Report |

3.0 Permitted activities

| | |
|---|--|
| Permitted activities | Details regarding permitted activities on the proposed site are provided in Section 2.1 of this SCR and Baseline Report. |
| Non-permitted activities undertaken | None |
| Document references for: <ul style="list-style-type: none">• plan showing activity layout; and• environmental risk assessment. | Appendix A – Site Plans ERA included as Appendix C to permit application |

3 STAGE 1 - IDENTIFY WHICH HAZARDOUS SUBSTANCES ARE USED, PRODUCED OR RELEASED AT THE INSTALLATION AND PRODUCE A LIST OF THESE SUBSTANCES

3.1.1 Stage 1 of the IED baseline assessment is to identify which hazardous substances are used, produced or released at the installation and to produce a list of these substances.

3.1.2 The IED relates to contamination risk associated with “hazardous substances” used at the facility. Hazardous substances are defined as substances or mixtures defined in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of substances and mixtures (the “CLP Regulations”). The CLP Regulations replace the Chemicals (Hazard Information and Packaging for Supply) regulations (“CHIP”). Substances hazardous to the environment as defined by the CLP Regulations relate to “Environmental Hazards” which in turn relates to aquatic toxicity, defined as follows (EU, 2013):

- Aquatic Acute 1 – H400: Very toxic to the aquatic life (Risk phrase R50);
- Aquatic Chronic 1 – H410: Very toxic to the aquatic life with long-lasting effects (Risk phrase R50/53);
- Aquatic Chronic 2 – H411: Toxic to the aquatic life with long-lasting effects (Risk phrase R51/53);
- Aquatic Chronic 3 – H412: Harmful to aquatic life with long-lasting effects (Risk phrase R52/53);
- Aquatic Chronic 4 – H413: May cause long lasting harmful effects to aquatic life (Risk phrase R52, R53).

3.1.3 The determination of whether a substance is a hazardous substance is largely determined using the substance CAS Number, substance safety data sheets and European Chemicals Agency (ECHA) database³. The substance specific safety data sheets can be found in Appendix D.

3.1.4 Details of all materials used and stored at the site are included in Table 3.1 below:

³ <https://echa.europa.eu>

Table 3.1 Materials Inventory

| Substance | CAS Number |
|---|-------------------|
| 1-Ethyl-3-(3-dimethylaminopropyl) carbodiimide hydrochloride | 25952-53-8 |
| 1,1-Carbonyldiimidazole (CDI) | 530-62-1 |
| 1-Propanol (Propyl alcohol) | 71-23-8 |
| 2-Propanol (sec-Propyl alcohol, Isopropyl alcohol, Isopropanol) | 67-63-0 |
| Acetone | 67-64-1 |
| Acetonitrile (methyl cyanide) (ACN) | 75-05-8 |
| Acetyl chloride | 75-36-5 |
| Ammonium chloride | 12125-02-9 |
| Benzyl chloroformate | 501-53-1 |
| Borane tetrahydrofuran complex solution | 109-99-9 |
| n-Butyllithium | 109-72-8 |
| Citric acid | 77-92-9 |
| Copper iodide | 7681-65-4 |
| Diethyl ether | 60-29-7 |
| Dimethylformamide | 68-12-2 |
| Diethyl ketone (3-Pentanone) | 96-22-0 |
| Diisopropyl ether (isopropyl ether) | 108-20-3 |
| Dimethyl sulphoxide (DMSO) | 67-68-5 |
| Dioxane (1,4-Dioxane) (Diethylene oxide) | 123-91-1 |
| Di-tert-butyl decarbonate (BOC anhydride) | 24424-99-5 |
| Ethanol | 64-17-5 |
| Ethyl acetate | 141-78-6 |
| Ethylene glycol (1,2-ethanediol) | 107-21-1 |
| n-Heptane | 142-82-5 |
| n-Hexane | 110-54-3 |
| Hydrazine hydrate | 10217-52-4 |
| Hydrochloric acid | 7647-01-0 |
| Hydrogen | 1333-74-0 |
| Iodomethane | 74-88-4 |
| Lithium chloride | 7447-41-8 |
| Lithium diisopropylamide | 4111-54-0 |

| Substance | CAS Number |
|--|------------|
| Methanol (Methyl alcohol) | 67-56-1 |
| Methyl chloroformate | 79-22-1 |
| Methyl ethyl ketone | 78-93-3 |
| Methyl propyl ketone (2-pentanone) | 107-87-9 |
| Methylene chloride | 75-09-2 |
| N-(3-Dimethylaminopropyl)-N'-ethylcarbodiimide hydrochloride | 25952-53-8 |
| Palladium tetrakis triphenylphosphine | 14221-01-3 |
| Phosphoryl chloride | 10025-87-3 |
| Potassium fluoride | 7789-23-3 |
| Potassium permanganate | 7722-64-7 |
| Pyridine | 110-86-1 |
| Sodium bicarbonate | 144-55-8 |
| Sodium chloride | 7647-14-5 |
| Sodium hydroxide | 1310-73-2 |
| Sodium hypochlorite | 7681-52-9 |
| Sodium sulphate | 7757-82-6 |
| Tert-butyl methyl ether (methyl tert-butyl ether) (MTBE) | 1634-04-4 |
| Tetrabutylammonium chloride (TABCl) | 1112-67-0 |
| Tetrahydrofuran (THF) | 109-99-9 |
| Thionyl chloride | 7719-09-7 |
| Trifluoroacetic acid | 76-05-1 |
| Toluene | 108-88-3 |
| Waste solvents | Various |
| m-Xylene (1,3-Dimethylbenzene) | 108-38-3 |

- 3.1.5 As well as the materials listed above, there will also be a number of waste materials produced or evolved dependant on the customer requirements for the API to be produced. The table shall be updated once the facility is commissioned and operational.
- 3.1.6 Of the materials stored and used at the facility, those substances that are designated hazardous substances or potentially contain hazardous substances defined by the ECHA database are shown in Table 3.2 below:

Table 3.2 Hazardous Materials Inventory

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|---|-----------------|-----------------------------|--|--|---|---|
| 1-Ethyl-3-(3-dimethylamino)propyl carbodiimide, hydrochloride | Solid | Soluble in water | Very toxic to aquatic life with long lasting effects | No data available | Not readily biodegradable in water. | H302 Harmful if swallowed H311 Toxic in contact with skin H315 Causes skin irritation H317 May cause an allergic skin reaction H319 Causes serious eye irritation H373 May cause damage to organs through prolonged or repeated exposure H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects |
| 1,1-Carbonyldiimidazole (CDI) | Powder Solid | Soluble in water | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H302 Harmful if swallowed H314 Causes severe skin burns and eye damage |
| 1-Propanol (Propyl alcohol) | Liquid | Completely miscible | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H318 Causes serious eye damage. H336 May cause drowsiness or dizziness. |
| 2-Propanol (sec-Propyl alcohol, Isopropyl alcohol, Isopropanol) | Liquid | Completely soluble | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. |
| Acetone | Liquid | Completely miscible | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. |
| Acetonitrile (methyl cyanide) (ACN) | Liquid | Completely soluble | Not classified as toxic to aquatic life | Not expected to adsorb on soil | Readily biodegradable | H225 Highly flammable liquid and vapour. H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled. H319 Causes serious eye irritation. |
| Acetyl chloride | Liquid | Reacts violently with water | Harmful to aquatic life | No data available | No data available | H225 Highly flammable liquid and vapour. H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. |
| Ammonium chloride | Solid | Soluble in water | Not classified as toxic to aquatic life | The product is water soluble and may spread in water systems. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils | Soluble in water, Persistence is unlikely, based on information available. Bioaccumulation is unlikely | H302 Harmful if swallowed H319 Causes serious eye irritation |

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|------------------------------|----------------|--|--|-------------------|--|---|
| Benzyl chloroformate | Liquid | No data available | Very toxic to aquatic life with long lasting effects | No data available | No data available | H314 Causes severe skin burns and eye damage. H410 Very toxic to aquatic life with long lasting effects |
| Borane tetrahydrofuran | Liquid | No data available | No data available | No data available | No data available | H225 Highly flammable liquid and vapour. H260 In contact with water releases flammable gases which may ignite spontaneously. H302 Harmful if swallowed. H318 Causes serious eye damage. H335 May cause respiratory irritation. H351 Suspected of causing cancer. |
| n-Butyllithium | Liquid | In contact with water releases flammable gases | Toxic to aquatic life with long lasting effects | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H225 Highly flammable liquid and vapour H250 Catches fire spontaneously if exposed to air H261 In contact with water releases flammable gases H304 May be fatal if swallowed and enters airways H314 Causes severe skin burns and eye damage H336 May cause drowsiness or dizziness H361f Suspected of damaging fertility H373 May cause damage to organs through prolonged or repeated exposure H411 Toxic to aquatic life with long lasting effects |
| Copper iodide | Solid | Insoluble | Very toxic to aquatic life with long lasting effects | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H302 Harmful if swallowed H315 Causes skin irritation H317 May cause an allergic skin reaction H318 Causes serious eye damage H335 May cause respiratory irritation H410 Very toxic to aquatic life with long lasting effects |
| Citric acid | Solid | Soluble in water | Not classified as toxic to aquatic life | No data available | No data available | H319 Causes serious eye irritation |
| Diethyl ether | Liquid | Slightly soluble in water (65 g/l at 20 °C) | Not classified as toxic to aquatic life | No data available | Not readily biodegradable | H224 Extremely flammable liquid and vapour. H302 Harmful if swallowed. H336 May cause drowsiness or dizziness. |
| Diethyl ketone (3-Pentanone) | Liquid | Slightly soluble in water (50 g/l) | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H335 May cause respiratory irritation H336 |

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|--|----------------|--|--|---|---|---|
| Di-isopropyl ether (isopropyl ether) | Liquid | Slightly soluble in water (3.11 g/l at 20.2 °C) | Not classified as toxic to aquatic life | No data available | Not biodegradable | May cause drowsiness or dizziness. H225 Highly flammable liquid and vapour. H336 May cause drowsiness or dizziness. |
| Dimethylformamide | Liquid | Soluble | Not classified as toxic to aquatic life | The product is water soluble and may spread in water systems Will likely be mobile in the environment due to its water solubility but will likely degrade over time. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils | Readily biodegradable Persistence is unlikely. Bioaccumulation is unlikely | H226 Flammable liquid and vapor H312 + H312 Harmful in contact with skin or if inhaled H319 Causes serious eye irritation H360D May damage the unborn child |
| Dioxane (1,4-dioxane) (diethylene oxide) | Liquid | Completely miscible | Not classified as toxic to aquatic life | No data available | Not readily biodegradable | H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H351 Suspected of causing cancer. |
| Di-tert-butyl decarbonate (BOC anhydride) | Liquid | No data available | No data available | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H226 Flammable liquid and vapour H315 Causes skin irritation H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H330 Fatal if inhaled. H335 May cause respiratory irritation |
| Ethanol | Liquid | Completely soluble in water | Not classified as toxic to aquatic life | The product is water soluble and may spread in water systems. | This substance is not classified as PBT or vPvB. Will not bio-accumulate. | H225 Highly flammable liquid and vapour. |
| Ethyl acetate | Liquid | Immiscible | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. |
| Ethylene glycol (ethanediol) | Liquid | Completely soluble | Not classified as toxic to aquatic life | No data available | Does not bioaccumulate. This substance/mixture contains no components considered to be either persistent, bio accumulative and toxic (PBT), or very persistent and very bio accumulative (vPvB) at levels of 0.1% or higher. | H302 Harmful if swallowed H373 May cause damage to organs (Kidney) through prolonged or repeated exposure if swallowed |
| n-Heptane | Liquid | Immiscible | Very toxic to aquatic life with long lasting effects | No data available | No data available | H225 Highly flammable liquid and vapour. H304 May be fatal if swallowed and enters airways. H315 Causes skin irritation. H336 |

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|----------------------------------|----------------|---------------------|---|--|--|--|
| | | | | | | May cause drowsiness or dizziness. H410 Very toxic to aquatic life with long lasting effects. |
| n-Hexane | Liquid | Insoluble | Aquatic Chronic 2 – H411: Toxic to the aquatic life with long-lasting effects (Risk phrase R51/53); | Aqueous solution has high mobility in soil | Readily degradable in the environment | H225 Highly flammable liquid and vapour. H304 May be fatal if swallowed and enters airways. H315 Causes skin irritation. H336 May cause drowsiness or dizziness. H361f Suspected of damaging fertility. H373 May cause damage to organs through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects. |
| Hydrazine hydrate | Liquid | No data available | Very toxic to aquatic life with long lasting effects. | No data available | No data available | H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H350 May cause cancer. H410 Very toxic to aquatic life with long lasting effects. |
| Hydrochloric acid (concentrated) | Liquid | Completely miscible | Not classified as toxic to aquatic life | No data available | No data available | H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage. H335 May cause respiratory irritation. |
| Hydrogen | Gas | 0.00196 g/l at 0 °C | No data available | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H220 Extremely flammable gas. H280 Contains gas under pressure; may explode if heated. |
| Iodomethane | Liquid | 8.66 g/l at 20 °C | Very toxic to aquatic life | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H226 Flammable liquid and vapour H301 + H331 Toxic if swallowed or if inhaled H312 Harmful in contact with skin H315 Causes skin irritation H319 Causes serious eye irritation H335 May cause respiratory irritation H351 Suspected of causing cancer H410 Very toxic to aquatic life with long lasting effects |
| Lithium diisopropylamide | Solid | No data available | No data available | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H250 Catches fire spontaneously if exposed to air H314 Causes severe skin burns and eye damage |

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|--|-------------------|--|--|------------------------------------|--|---|
| Methanol (methyl alcohol) | Liquid | Completely miscible | Not classified as toxic to aquatic life | Will not adsorb on soil | Readily biodegradable | H225 Highly flammable liquid and vapour. H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled. H370 Causes damage to organs (Eyes). |
| Methyl chloroformate | Liquid | No data available | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H302 + H312 Harmful if swallowed or in contact with skin H314 Causes severe skin burns and eye damage. H330 Fatal if inhaled. |
| Methyl ethyl ketone | Liquid | Soluble | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. |
| Methyl propyl ketone (2-Pentanone) | Liquid | Moderate | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour H302 Harmful if swallowed H319 Causes serious eye irritation H335 May cause respiratory irritation |
| Methylene chloride (dichloromethane) (DCM) | Liquid | Slightly soluble (13.2 g/l at 25 °C) | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H315 Causes skin irritation. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H351 Suspected of causing cancer. |
| Phosphoryl chloride | Liquid | Reacts violently with water. Contact with water liberates toxic gas. | Product reacts with water. Depending on the concentration, phosphorus compounds may contribute to the eutrophication of water supplies | No information available | No information available | H302 Harmful if swallowed H314 Causes severe skin burns and eye damage H330 Fatal if inhaled H372 Causes damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled. |
| Potassium fluoride | Crystalline Solid | Soluble in water | Not classified as toxic to aquatic life | Low potential for mobility in soil | Not applicable | H301 Toxic if swallowed |
| Potassium permanganate | Solid | Soluble in water | Very toxic to aquatic life with long lasting effects | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H272 May intensify fire; oxidizer H302 Harmful if swallowed H314 Causes severe skin burns and eye damage H410 Very toxic to aquatic life with long lasting effects |
| Pyridine | Liquid | Soluble | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled H315 |

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|--|-------------------|--|--|---|--|---|
| | | | | | | Causes skin irritation. H319 Causes serious eye irritation |
| Sodium hydroxide | Crystalline Solid | Exothermically soluble in water | Harmful to aquatic life | No data available | Not applicable | H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. H402 Harmful to aquatic life |
| Sodium hypochlorite | Liquid | Soluble | Very toxic to aquatic life with long lasting effects | The product is water soluble and may spread in water systems Will likely be mobile in the environment due to its water solubility. Highly mobile in soils | Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB). Bioaccumulation is unlikely | H290 May be corrosive to metals H314 Causes severe skin burns and eye damage H318 Causes serious eye damage. H400 Very toxic to aquatic life H411 Toxic to aquatic life with long lasting effects causes severe skin burns and eye damage, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and causes serious eye damage. |
| Tert-butyl methyl ether (methyl tert-butyl ether) (MTBE) | Liquid | Moderately soluble in water 42 g/l at 20 °C | Not classified as toxic to aquatic life | No data available | Not readily biodegradable | H225 Highly flammable liquid and vapour. H315 Causes skin irritation. |
| Tetrabutylammonium chloride (TABC1) | Crystalline | Soluble | Not classified as toxic to aquatic life | No data available | No data available | H315 Causes skin irritation. H319 Causes serious eye irritation. |
| Tetrahydrofuran (THF) | Liquid | Miscible | Not classified as toxic to aquatic life | No data available | Not readily biodegradable | H225 Highly flammable liquid and vapour. H302 Harmful if swallowed. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H351 Suspected of causing cancer. |
| Thionyl chloride | Liquid | Contact with water liberates toxic gas | No data available | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | H302 Harmful if swallowed H314 Causes severe skin burns and eye damage H331 Toxic if inhaled |
| Toluene | Liquid | Insoluble in water 0.5 g/l at 15 °C | Not classified as toxic to aquatic life | No data available | Readily biodegradable | H225 Highly flammable liquid and vapour. H304 May be fatal if swallowed and enters airways. H315 Causes skin irritation. H336 May cause drowsiness or dizziness. H361d Suspected of damaging the unborn child. H373 May cause damage to organs through prolonged or repeated exposure. |
| Trifluoroacetic acid | Liquid | Soluble. Exothermic in contact with water | Harmful to aquatic life with long lasting effects | No data available | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very | H314 Causes severe skin burns and eye damage H332 Harmful if inhaled |

| Substance | Physical State | Water Solubility | Toxicity | Mobility in Soil | Persistence | Hazard Statements |
|-----------------------------------|----------------|------------------|--|---|---|--|
| | | | | | persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. No bioaccumulation is to be expected | H412 Harmful to aquatic life with long lasting effects |
| Waste solvents | Liquid | n/a | n/a | n/a | n/a | As above |
| m-Xylene (1,3-Dimethylbenzene) | Liquid | Slightly soluble | Aquatic Chronic 3 – H412: Harmful to aquatic life with long-lasting effects (Risk phrase R52/53); | Will likely be mobile in the environment due to its volatility. Is not likely mobile in the environment due its low water solubility. | Persistence is unlikely | H226 Flammable liquid and vapour. H304 May be fatal if swallowed and enters airways. H312 + H332 Harmful in contact with skin or if inhaled. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects. |

4 STAGE 2 – IDENTIFYING THE RELEVANT HAZARDOUS SUBSTANCES'

- 4.1.1 Stage 2 of the IED baseline assessment is to identify the RHSs from those identified in the stage 1 assessment.
- 4.1.2 On the basis of hazardous substances identified above, those considered to be RHS must be defined. Those hazardous substances that are incapable of contaminating soil or groundwater can be disregarded for further consideration although a justified reason for exclusion must be provided.
- 4.1.3 All solvents to be used at the site will be stored in the outside chemical storage container in containers up to 25 L in size with the exception of tetrahydrofuran which is stored in a 50 L container. Solvents used for cleaning (acetone/methanol/propanol) will be stored in containers up to 205 L in size. Solvents will also be stored in the internal flammable store during use in the reaction processes. These will only be stored for limited time during use.
- 4.1.4 Monopropylene glycol is used as a chilling media and will be used in the closed loop system and contained within the chiller unit. These units are located adjacent to the back of the building on hardstanding areas away from any vehicle movements etc. They will be topped up when required but generally this will be infrequent and therefore movements of monopropylene glycol will be minimal to reduce risk of spillages etc.
- 4.1.5 Based on the properties of the solvents to be used (water solubility and persistence), the following are considered relevant hazardous substances (RHSs):
- Diethyl ether;
 - Diethyl ketone;
 - Diisopropyl ether;
 - Dioxane;
 - Ethyl acetate;
 - n-Heptane;
 - n-Hexane;
 - Methylene chloride;
 - Tert-butyl methyl ether;
 - Tetrahydrofuran;
 - Toluene; and
 - m-Xylene;
- 4.1.6 It is assumed that there will be one campaign ongoing at any one time, using two 100L vessels. It is estimated there would be a requirement to store approximately 2,500L of flammable solvent and 240kg assorted non-solvent raw materials (including regulated starting material (RSM), reagents and inorganics) at any one time.
- 4.1.7 Solvent volumes are anticipated to fluctuate depending on the process and associated cleaning requirements. A stock of cleaning solvents would always be kept on site.
- 4.1.8 The following waste streams produced at the site are classified as hazardous and maybe considered as RHSs for this assessment. These have been listed above as waste solvents:
- 07 05 01 - aqueous washing liquids and mother liquors: Filtrations, Cake washes, Vessel and Equipment Cleaning, Scrubber Liquors, Liquid-Liquid Extractions.

-
- 07 05 03 - organic halogenated solvents, washing liquids and mother liquors: Filtrations, Cake washes, Distillate, Vessel and Equipment Cleaning, Liquid-Liquid Extractions.
 - 07 05 04 - other organic solvents, washing liquids and mother liquors
 - 07 05 07 - halogenated still bottoms and reaction residues Halogenated process or cleaning solvents as per 07 05 03 sources.
 - 07 05 08 - other still bottoms and reaction residues

4.1.9 The following raw materials to be used are not considered as relevant hazardous substances as they will be stored and used within Building 901 in sealed bunded areas in flammable stores (if required) and stored in comparatively small quantities (500g, 1kg or 5kg containers with the exception of citric acid and sodium chloride which will be stored in up to 25kg containers. Liquids shall be stored in up to 5 litre containers).

- 1-Ethyl-3-(3-dimethylaminopropyl) carbodiimide. Hydrochloride;
- Acetyl chloride;
- Ammonium chloride;
- Benzyl chloroformate;
- Boc anhydride;
- Borane-THF;
- Carbonyldiimidazole;
- Copper iodide;
- Citric acid;
- Hydrazine hydrate;
- Iodomethane;
- Lithium diisopropylamide;
- n-butyllithium;
- Phosphoryl chloride
- Potassium fluoride;
- Pyridine;
- Sodium hydroxide;
- Sodium hypochlorite;
- Tetrabutylammonium chloride;
- Thionyl chloride; and
- Trifluoroacetic acid

4.1.10 There is a secure hardstanding area outside which will be used for gas storage. As hydrogen will be stored externally, it is not classed a relevant hazardous substance.

5 STAGE 3 – ASSESSMENT OF THE SITE-SPECIFIC POLLUTION POSSIBILITY

5.1 Site-Specific Pollution Possibility

5.1.1 Stage 3 of the IED baseline assessment is to assess the site-specific pollution possibility.

5.1.2 The evaluation of the possibility of contamination occurring in relation to RHS has been termed an assessment of “site-specific pollution potential”. A qualitative, desk based, approach has been used to determine site-specific pollution potential. This approach involves the following steps:

- Summary of all potentially hazardous substances used, produced and/or emitted at the proposed facility (Substance Inventory) and the associated processes, storage, use and handling thereof;
- Determination of which substances constitute RHSs as defined by IED;
- Identification of possible release scenarios and associated mitigation measures incorporated into design and/or operational measures (e.g. through EMS) developed for the facility;
- Consideration of CSM to determine whether a plausible pollutant linkage exists that could connect the contamination source to soil or groundwater receptors; and
- Assessment of site-specific pollution potential using a qualitative risk matrix approach.

5.1.3 The site-specific pollution potential is dependent on the CSM developed for the facility using the concept of pollutant (Source-Pathway-Receptor) linkages, which in turn is dependent on the conceptual hydrogeology and ground model of the system. An active pollutant linkage enables known or potential contamination sources to be linked with a specific environmental receptor via a plausible transport pathway.

5.1.4 The pollutant linkages defined for the CLS installation are therefore dependent on the nature of potential release scenarios associated with each RHS and the nature of any pollution prevention measures or mitigation measures implemented on the site (e.g. through facility design / engineering, nature of on-site containment, emergency response measures, routine inspection / maintenance protocols etc.).

5.2 Risk Matrix for Determining Site-Specific Pollution Potential

5.2.1 Following identification of the RHSs, a risk matrix approach has been developed that considers the likelihood of an accidental release occurring and the likelihood of the soil or groundwater receptor being affected.

Likelihood of Accidental Release / Emission Occurring

5.2.2 By consideration of the processes that each RHS is used in (in terms of storage / handling / use) and the measures implemented at the CLS installation to minimise the potential of a release to occur (during routine use or by accidental emission), the likelihood of a release that could potentially affect a receptor is assessed as follows:

- **Highly Likely:** A process involving the RHS that is not controlled and the RHS could be readily be lost to ground / air / water without mitigation. Nature of handling / storage of the RHS and absence of mitigation measures makes the potential for an accidental emission / release probable;
- **Likely:** The process involving the RHS or the manner of RHS handling / storage is likely to result in a loss to ground, air or water. However, the activities involving the RHS include mitigation measures and/or are undertaken in an engineered / designed facility. The condition of equipment and infrastructure (e.g. storage tanks) is poor, cannot be verified or is poorly

maintained. There are no control measures and/or associated staff training to mitigate an accidental release.

- **Unlikely:** Owing to the nature of the process and/or characteristics of the RHS, release scenarios are considered improbable. The process does not involve the RHS being exposed or used in a high-risk manner (e.g. storage of small quantities in bunded or sealed areas) and there are measures to prevent release including in design (e.g. secondary / tertiary containment, sealed drainage, impermeable membranes). The quantities used are small and manageable. Site records demonstrate the absence of any accidental releases occurring. The condition of equipment and infrastructure (e.g. storage tanks) is good and well maintained. There are robust control measures and/or associated staff training to mitigate accidental release; and
- **Very Unlikely:** As for “unlikely” but the probability of release is considered to be lower.

Likelihood of Receptor being Affected

5.2.3 For a named receptor (i.e. soil or groundwater), the likelihood of an accidental release affecting the receptor is determined. The receptor likelihood classes used in this qualitative assessment are as follows:

- **Highly Likely:** A direct, active pollutant linkage exists. A large quantity of the RHS is used in a mobile form relevant to the receptor. There is an absence of mitigation measures to control the release or emergency response should accidental emission occur. There is an absence of any other attenuation measures that may mitigate the release before the receptor is affected.
- **Likely:** An active pollutant linkage exists. The quantity of used product or manner of its use may render pollution prevention measures ineffective. The condition or implementation of pollution prevention control measures is poor or cannot be verified. There are historical incidences of accidental releases that affect the receptor.
- **Unlikely:** A possible pollutant linkage exists but is either complex / indirect or has characteristics likely to mitigate any releases. The quantity of material released is likely to be small or of a form unlikely to reach the receptor. It requires a secondary process to be present before the receptor can be affected (e.g. solid going into solution);
- **Very Unlikely:** Although a theoretical pathway to a receptor can be envisaged it is considered extremely unlikely to be active, although cannot be discounted entirely.

5.2.4 These two key elements of the risk assessment are combined using the risk matrix presented in Table 5.1 below:

Table 5.1: Risk Matrix for Determining Site-Specific Pollution Potential

| | | Likelihood of Receptor Being Affected by Release | | | |
|---------------------------------|---------------|--|----------|---------------|---------------|
| | | Highly Likely | Likely | Unlikely | Very Unlikely |
| Likelihood of Release Occurring | Highly Likely | Extremely High | High | High | Moderate |
| | Likely | High | High | Moderate | Low |
| | Unlikely | High | Moderate | Low | Extremely Low |
| | Very Unlikely | Moderate | Low | Extremely Low | Negligible |

5.2.5 Where no plausible linkages have been identified that can connect a contaminant source with a named receptor, a risk classification of “negligible” is applied.

5.2.6 The receptors to be considered are:

-
- Near surface soils principally in landscaped areas that are not covered by permanent hardstanding (Soil – Landscaped);
 - Soils that form the unsaturated zone principally in areas covered by permanent hardstanding and/or structures at the CLS installation (Soil – Subsurface);
 - Productive Bedrock Aquifer, Unproductive Superficial Aquifer

5.2.7 The risk matrix approach does not consider the magnitude or severity of any effect that may occur should the release scenario and associated pollutant linkage be realised. It is assumed that the process for the identification of RHS should provide an adequate assessment of whether the quantities of the substance used at the CLS installation have the potential to result in a measurable impact on the receptors in question.

5.3 Site Location

5.3.1 The site is located within Discovery Park and is located on Ramsgate Road approximately 1.2km to the north of the town of Sandwich, Kent. Further details on the site location can be found in section 2.

5.3.2 The site is relatively flat and located at approximately 2m above Ordnance Datum (m AOD).

5.3.3 Site location plans can be found in Appendix A.

5.4 Proposed Operations and Layout

5.4.1 All production process activities shall be carried out within the building itself; this includes the storage of raw materials and products.

5.4.2 There will be external storage areas for solvents which will be located on impermeable hardstanding and utilise self-bunded flammable storage containers in kerbed areas. These areas drain to the external surface water catch pit.

5.4.3 Details of site activities can be found in Table 5.2 below:

Table 5.2 Description of Activities

| Activity | Procedure | Emissions | Spillages |
|--|--|--|---|
| Delivery of raw materials | <p>Materials are received at the front gate on pallets.</p> <p>Solvents are either transferred to the outside secure bunded storage area or transferred inside via the scissor lift and stored in the raw materials of flammables store.</p> <p>Solids and liquid reagents are also transferred to the inside raw materials store via the scissor lift.</p> | <p>No emissions unless spillage occurs.</p> <p>Material is contained throughout its movement.</p> | <p>Spillage kit will be available adjacent to the front gate for responding to liquid or solid spills.</p> <p>Liquid spillage within the outside area would run off into surface drains located at either gate or under scissor lift.</p> <p>Surface drains lead to building 287 effluent pit where liquid could be segregated. This pit is managed by Pfizer</p> |
| Dispensing and charging solids | <p>Solids will be dispensed into sealed transfer containers within a fume cupboard (FC) located in the Dispensary and raw materials storeroom.</p> <p>They will then be transported to the vessel and charged via charging port on the man way.</p> | <p>Dust will be contained within the fume hood.</p> <p>When charged to the vessel, any dust will be extracted FC.</p> | <p>Spillages on route from the dispensary to the vessel will be dealt with according to the material safety data sheet (MSDS) for the material.</p> <p>Spill kits will be available inside the building. Dry spills are contained using booms if necessary and swept into containers for incineration</p> |
| Dispensing and charging liquids | <p>Two different procedures:</p> <ol style="list-style-type: none"> Solvent supplied in 2.5L Winchester, which will be taken to the vessel and charged under dead vacuum via lance & hoses within the FC. Solvent supplied in 200L drums. Drum placed in FC and pumped into either 20L or 50L steel canisters. These will be then taken to the vessel FC and charged as above or stored within the flammables storeroom for later use. | <p>Handling of open containers within fume cupboards only.</p> <p>Once charged to the vessel, solvent will be condensed by the reactor condensers or captured by the scrubber.</p> | <p>Any spillage within the storeroom, corridor, reactor hall or fume cupboard will be captured by potentially contaminated (PC) or chemically contaminated (CC) drain lines which are capped and therefore form a bund where the solvent could be segregated and disposed of. External drains are capped.</p> |
| Transfer between two vessels | <p>Hoses connected from vessel to the receiver vessel (possibly via contained filter housing). Nitrogen over-pressure will push the liquid from one vessel to the other. All equipment will be held within the fume cupboard.</p> | <p>Vessels either vented to fume cupboard or scrubbers via condensers.</p> <p>Displacement of head space in receiver vessel.</p> | <p>Leak from hoses (or filter). As above, leak would be captured by CC drain in fume cupboard and retained in bund. External drains are capped.</p> |
| Discharge of liquid from vessel to waste container | <p>Hose will be connected from the base of the vessel to a lance placed in a waste container within the fume cupboard.</p> | <p>Displacement of head space in the waste container.</p> | <p>Leak from hoses.</p> <p>As above, leak would be captured by CC drain in fume cupboard and retained in bund. External drains are capped.</p> |
| Vacuum Distillation | <p>If vacuum is required, it is applied to the receiver, following which the contents of the vessel are heated until boiling. Solvents are condensed and collected in the receiver.</p> | <p>Solvent condensed by vessel condensers. Vacuum pumps are fitted with condensers.</p> | <p>Distillation pipe work all contained within fume cupboard.</p> <p>FC bunded.</p> |

| Activity | Procedure | Emissions | Spillages |
|--------------------------------|---|---|--|
| | Vacuum is pulled from downstream of the condensers. Any solvent reaching vacuum pump will be captured within the vacuum pump condenser. catch pot downstream of pump. Vacuum pump is vented to the fume hood | | |
| Filtration | As per "Transfer between two vessels." Liquors will be returned to another vessel or directly discharged to waste containers. | Filtration closed system. Discharge of liquors using hoses - Displacement of head space in the waste container. | Leak from hose. As above, leak would be captured by CC drain in fume cupboard. External drains are capped. |
| Transfer from filter to oven | Damp solids transferred in polythene bags. Bags placed in glove box and solid loaded into drying trays within glove box. | Little potential for emission of solids from filter as damp. Transfer to take place inside FC. | As per "Dispensing and charging solids." |
| Drying | Vacuum applied to oven from local oven vacuum pump. Solvent evaporates and is condensed by heat exchanger on vacuum pump catch pot. | Solvents drawn from damp solid condensed in catch pot. Solids removed by High-efficiency particulate air filter (HEPA) filter on oven. When required, HEPA filters are replaced. | Any spillages will be contained within the glove box. Glove box is physically connected to the oven. |
| Packaging | Product is removed from the oven and dispensed and sealed into polythene bags. Polythene bags are removed from the glove box via a liner and are then placed and sealed in kegs. | Glove box is HEPA filtered, therefore no emission. | Product contained in glove box during packaging steps. |
| Removal of waste from building | (Contaminated) solid waste will be double bagged, sealed and placed in the relevant waste storage bin outside the building to be collected by the onsite waste disposal contractor. | Waste will be bagged inside the building (inside fume cupboard if necessary), therefore low risk of emission. | Spillages will be dealt with according to the MSDS for the contaminating material (if applicable). Spill kits available. Dry spills are contained using booms if necessary and swept into containers for incineration |

-
- 5.4.4 It is estimated that there would be a maximum of approximately 2500L flammable solvent and 240kg assorted non-solvent raw materials (including RSM, reagents and inorganics) stored at any one time.
- 5.4.5 Solvent volumes are made up of solvent required for cleaning and therefore not campaign specific (a stock of these would be kept on site at all times, these include Methanol, Acetone and IPA) and campaign specific solvents (dependent on nature of chemistry campaign(s)).
- 5.4.6 Solvent containers could range in size from 2.5 L Winchesters up to 25 L steel drums. For common cleaning solvents (acetone and methanol), 205 L steel drums could be utilised.
- 5.4.7 Bulk solids can be supplied in plastic bags or kegs up to 25kg. Typically, reagents and chemicals are supplied in 1 kg/1 L bottles or smaller.
- 5.4.8 APIs, intermediates and RSMs will be packaged in kegs or drums up to 5kg.

Surface Water Drainage System

- 5.4.9 The surface water drainage system for the facility is shown in the site plans in Appendix A.
- 5.4.10 All surface water from the facility drains to the Discovery Park wastewater treatment plant (WWTP). If there was a spillage of chemicals, these could be isolated either at the facility or at the WWTP. Procedures are in place to alert the WWTP of any onsite incident which could potentially allow contaminated materials to drain to the WWTP.
- 5.4.11 There are no direct releases from surface water drainage discharges into the River Stour or groundwater. Any surface water that goes to the WWTP will eventually be discharged into the River Stour following treatment.

Potential Release Scenarios

- 5.4.12 Potential release scenarios for the RHS used on the CLS site are summarised below:
- Accidental release of substances during their use, transport and/or storage on the facility. Principally associated with solvents and raw materials stored in small quantities both internally and externally. Typically stored in internal bunded chemical stores or external self-bunded flammable stores;
 - Fugitive emissions caused by flooding or fire/firewater.

Pathways and Associated Pollution Prevention Measures

- 5.4.13 The general pollution prevention and/or mitigation measures associated with processes and RHS used, produced or emitted at the facility are described in the Environmental Risk Assessment (ERA) in Appendix C to the Permit Variation Supporting Information document and comprise the following:
- No underground storage tanks are in place or proposed for the facility;
 - The raw materials and products are stored within a bunded building which have bunded storage areas as shown in figure 5-2 below. The building has sealed internal drainage and impermeable floors.
 - All external solvent stores are situated on impermeable made ground to prevent fugitive emissions to ground should spills/ leaks occur. These areas are surrounded by kerbing which is itself situated lower than the surrounding gravelled areas.
 - All chemicals will be subject to appropriate storage and handling practices which are described and enforced through the CLS Environmental Management System (EMS) and standard operating procedures (SOP).

-
- The site has a spillage procedure to ensure that any risk from spillages is minimised and are cleaned up as soon as a spill is detected. Emergency spill kits will be available across the site
 - Accidental spills in external areas could potentially enter the surface water drainage system shown in the drainage plans in Appendix A of this report. The effects of accidental spills are mitigated by surface water systems draining to the Discovery Park WWTP where they can be isolated.

Product handling and storage

- 5.4.14 B901 has a dedicated storage area for chemical reagents, intermediate compounds and final API products. The area is access controlled. The store additionally contains two chemical storage cabinets to allow for chemical segregation of hazardous materials such as oxidising agents and flammable solids
- 5.4.15 The facility has a separate internal solvent storeroom which is bunded and fitted with ATEX rated equipment. This room has appropriate racking for storage of solvents and solvent jerry cans to allow for solvents to be dispensed to volumes required for use. There is an external solvent/flammable stores.
- 5.4.16 The storage area has an extract fume cupboard to allow for the handling opening, sampling and dispensing of materials for use. Manufacturing records indicate the required quantities for the batch process to allow minimum inventory dispensing.
- 5.4.17 Materials enter the building via an access-controlled door and can be removed from transportation package within the building. Material movement from the store to the reaction vessels is all internal to the building.
- 5.4.18 The production team have job descriptions and all chemist roles are at graduate or higher level with a science degree. The team have emergency spill responders.

Minimisation of environmental impact

- 5.4.19 B901 contains reaction vessels of 50 to 100 litres capacity. The vessels are enclosed, housed within walk-in fume hoods, and vent via process scrubber. The reaction vessels are equipped with burst disc relief to a dedicated catch tank with level detection. The inlets and outlets of the vessel include fittings to allow hose or powder transfer connections for closed transfer of liquids and powders. Storage containers are UN approved and are closed when not in use
- 5.4.20 All reactors are equipped with vessel jackets to control temperature using heat transfer fluid and the thermostat units that supply the heat transfer fluid have independent temperature control
- 5.4.21 All reactors are ATEX rated and are equipped to handle flammable solvents. All reaction vessels are fitted with condensers to enable solvent recovery and minimisation of VOC emission to the process vent. The condensers have duty and standby thermostat units circulating cold heat transfer fluid with programmable temperature set points to minimise solvent emissions
- 5.4.22 All of the condensers vent to the building process scrubber that provides further abatement capability
- 5.4.23 The reactors are enclosed within fume hoods. The fume hoods have duty and standby extract fans and have velocity control with alarm indication. The building is equipped with a supply air fan.
- 5.4.24 API manufacture is conducted on a batch by batch basis and the process technology package identifies the process waste streams and appropriate segregation and storage of each of the process waste streams. Wastewater streams from the process are identified and segregated in this manner
- 5.4.25 The reaction vessels are controlled by a process logic control system which enables a stable controllable operation.

Ground protection

- 5.4.26 The facility is sited within a secure site and the area of material off load is on a tarmac covered area behind a fence line under the organisations control. Procedures will be in place to unload containers from approved transports. The area is equipped with spill containment and the organisation has a spill response team. All areas within the building have impermeable sealed surfaces and sealed drainage.
- 5.4.27 Inventory size and containers are controlled. The vessels are typically 100 L in fill capacity so liquids will be provided in drum containers and not bulk delivery thus minimising the scale.
- 5.4.28 Within the facility the solvents are held in a bunded area with impermeable surfacing. The vessels are housed within fume hoods that have contained drains. In the event of a spill from the vessel the material enters a contained bund and held prior to recovery and disposal. The fume hoods have chemically resistant tiled flooring.
- 5.4.29 Vessels are engineering qualified before use and subjected to ongoing maintenance and leak testing.

Enclosure of sources

- 5.4.30 The materials are stored in united nations (UN) approved containers and dispensed in a fume hood to the required quantity prior to use. These sublots are then moved local to the reactor for charging to the vessel. The vessels are located within fume hoods equipped with extract ventilation. The facility also has a glovebox suitable to prepare and dispense powders.
- 5.4.31 Figures 5.1 to 5.6 below show the raw material flow and storage arrangements:

Figure 5-1: Raw Materials Flow

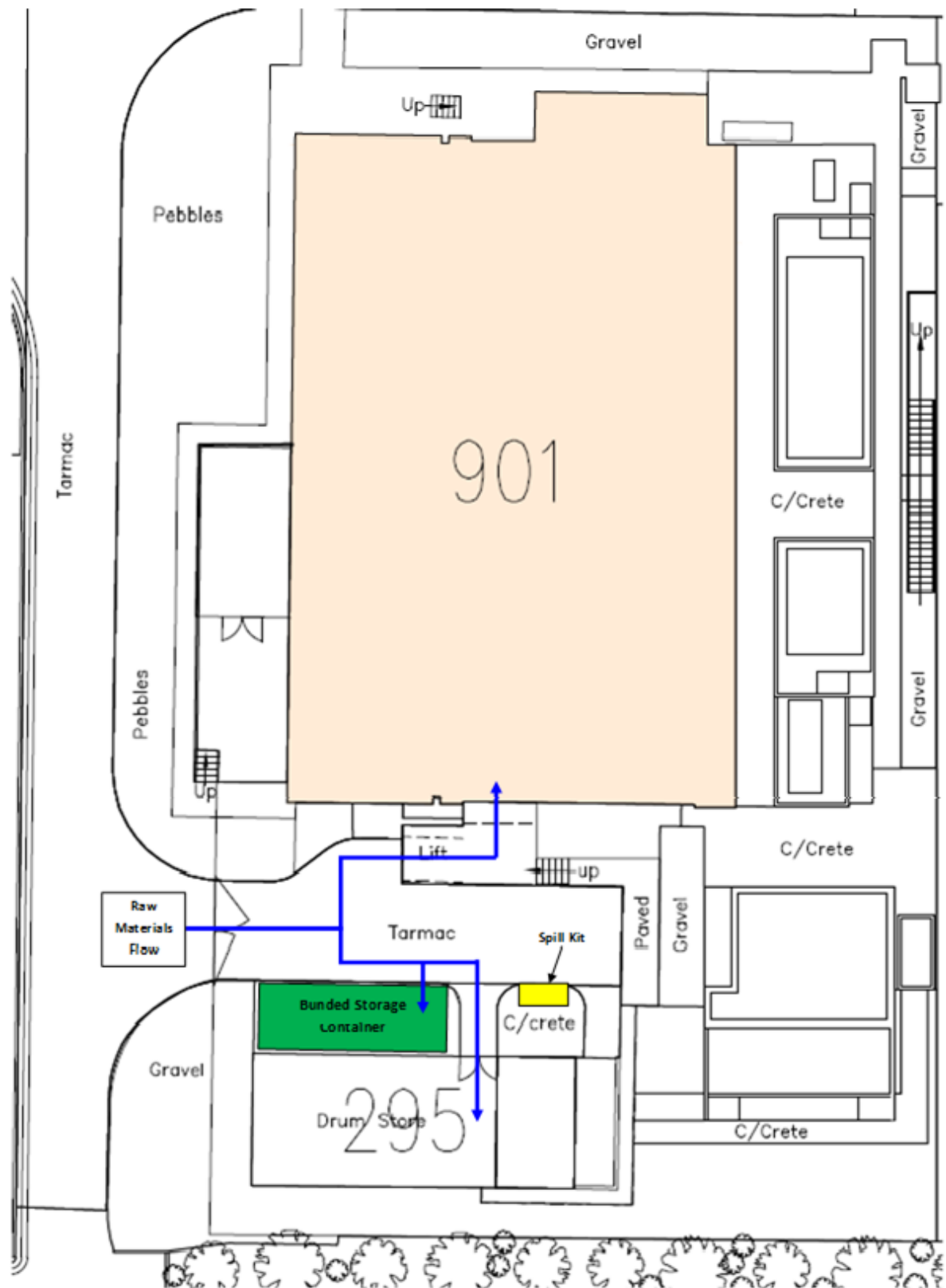


Figure 5-2: Raw Materials Storage

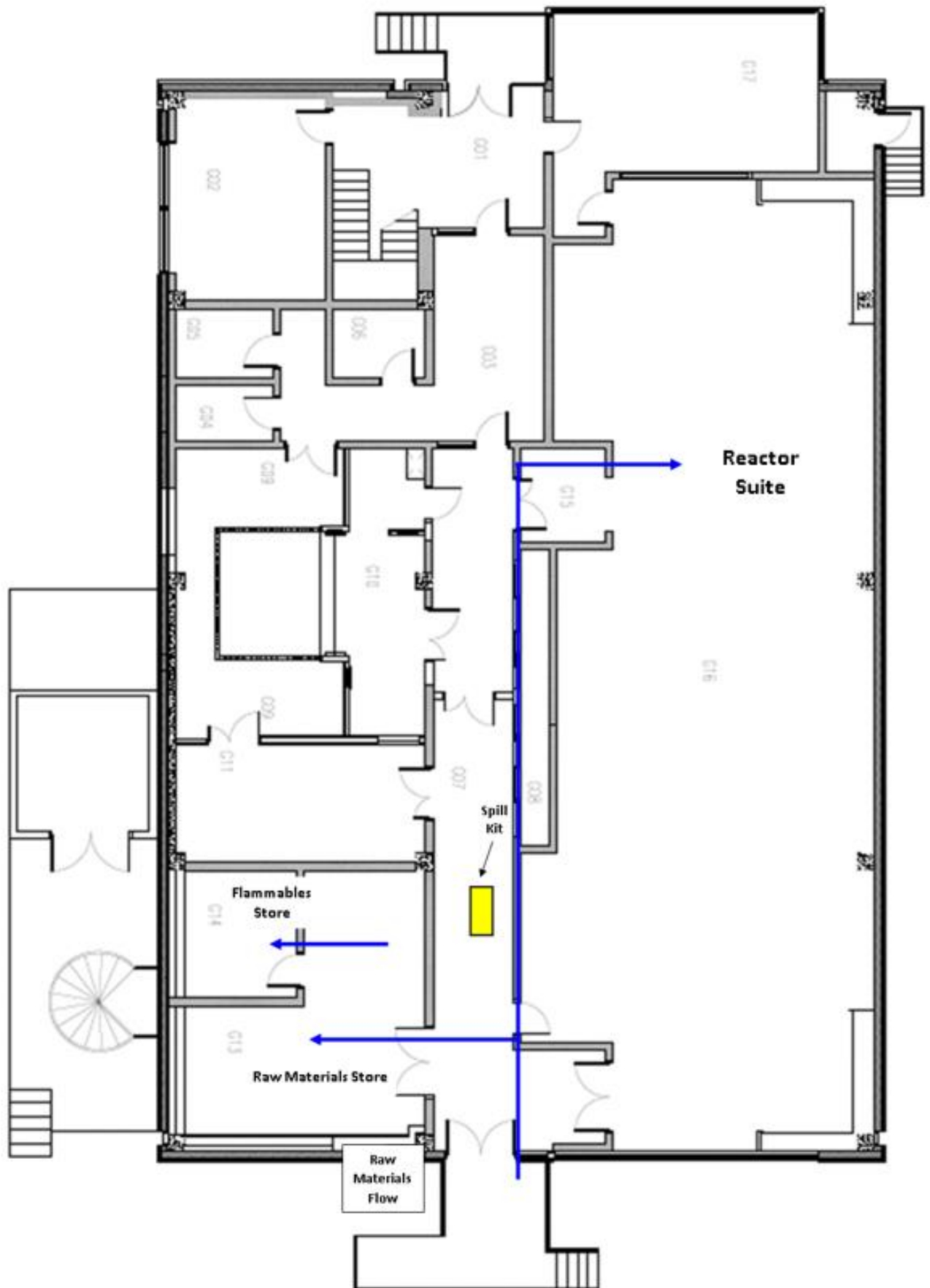


Figure 5-3: Internal Storage Area

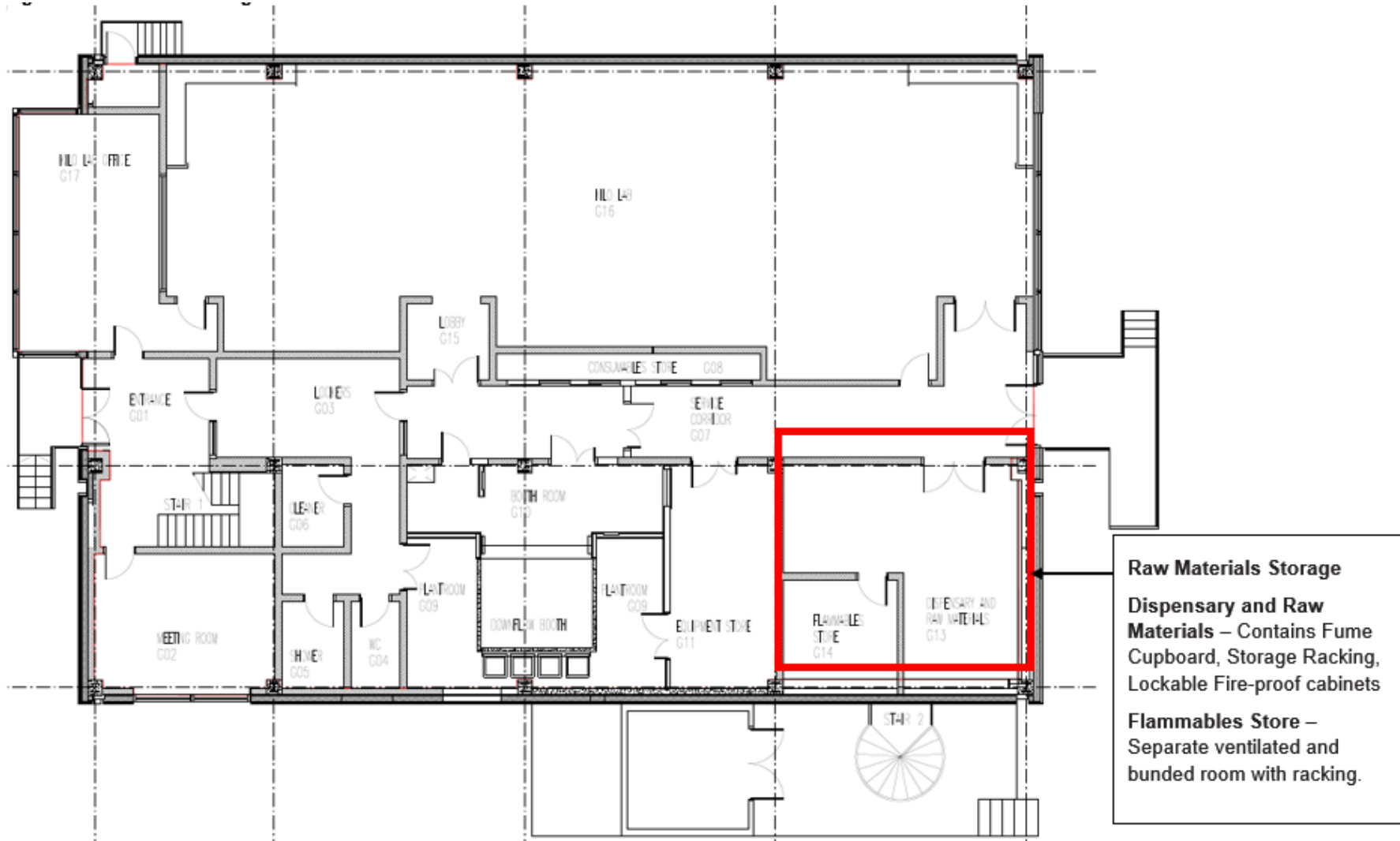
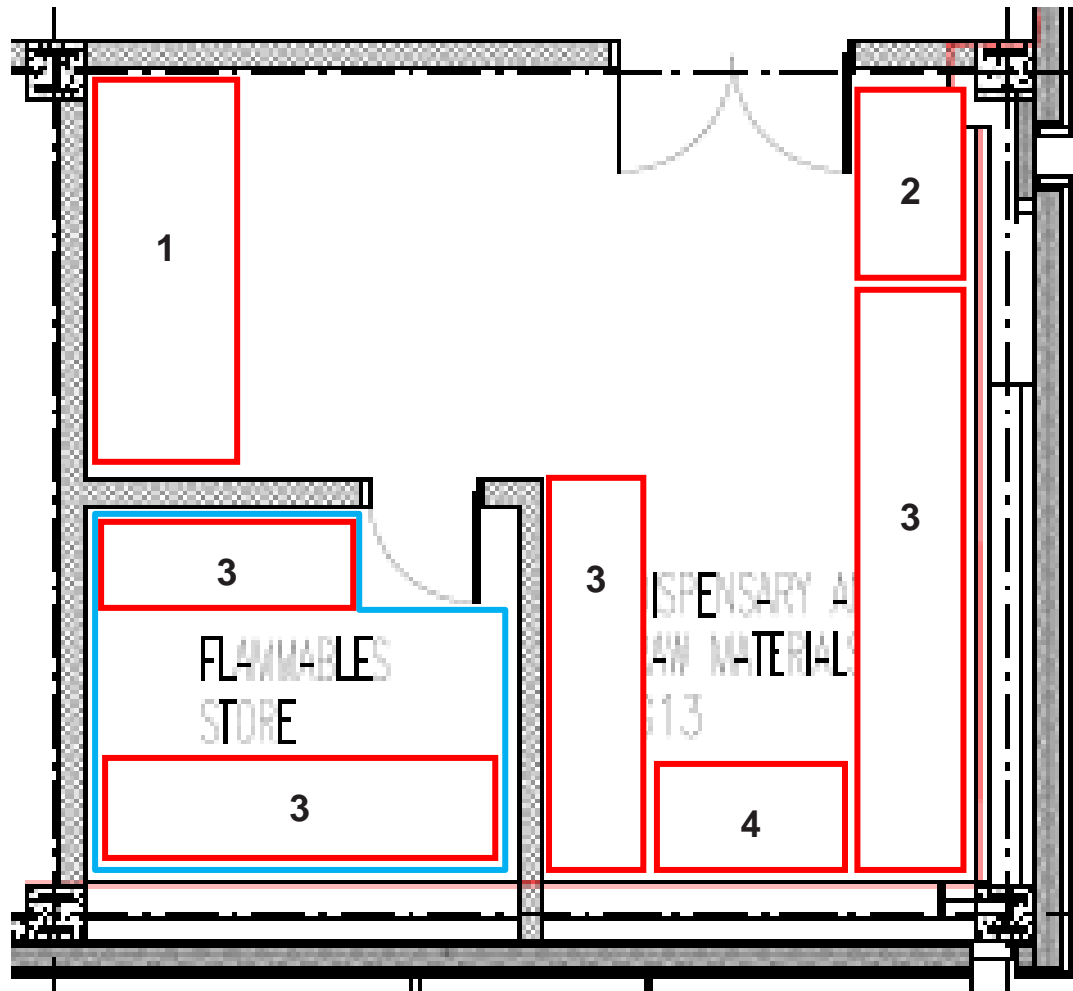


Figure 5-4: Breakdown of anticipated storage utilisation and bund arrangement



Dispensary and Raw Materials

1. **Fume cupboard for raw material sampling and dispensing.**

2. **Lockable fireproof cabinet for oxidising agents.**

Anticipated max storage = 15Kg

3. **Storage racking for raw materials, reagents and finished product.**

Anticipated max storage = 200Kg

4. **Lockable fireproof flammable solids cabinet.**

Anticipated max storage = 15Kg

Flammables storeroom has an internal concrete bund of 950L encompassing the room and racking. Anticipated maximum storage in this area is 800L.

Both rooms are ventilated and extracted with heat sensors for fire detection.

Figure 5-5: External Storage Areas and Bunds

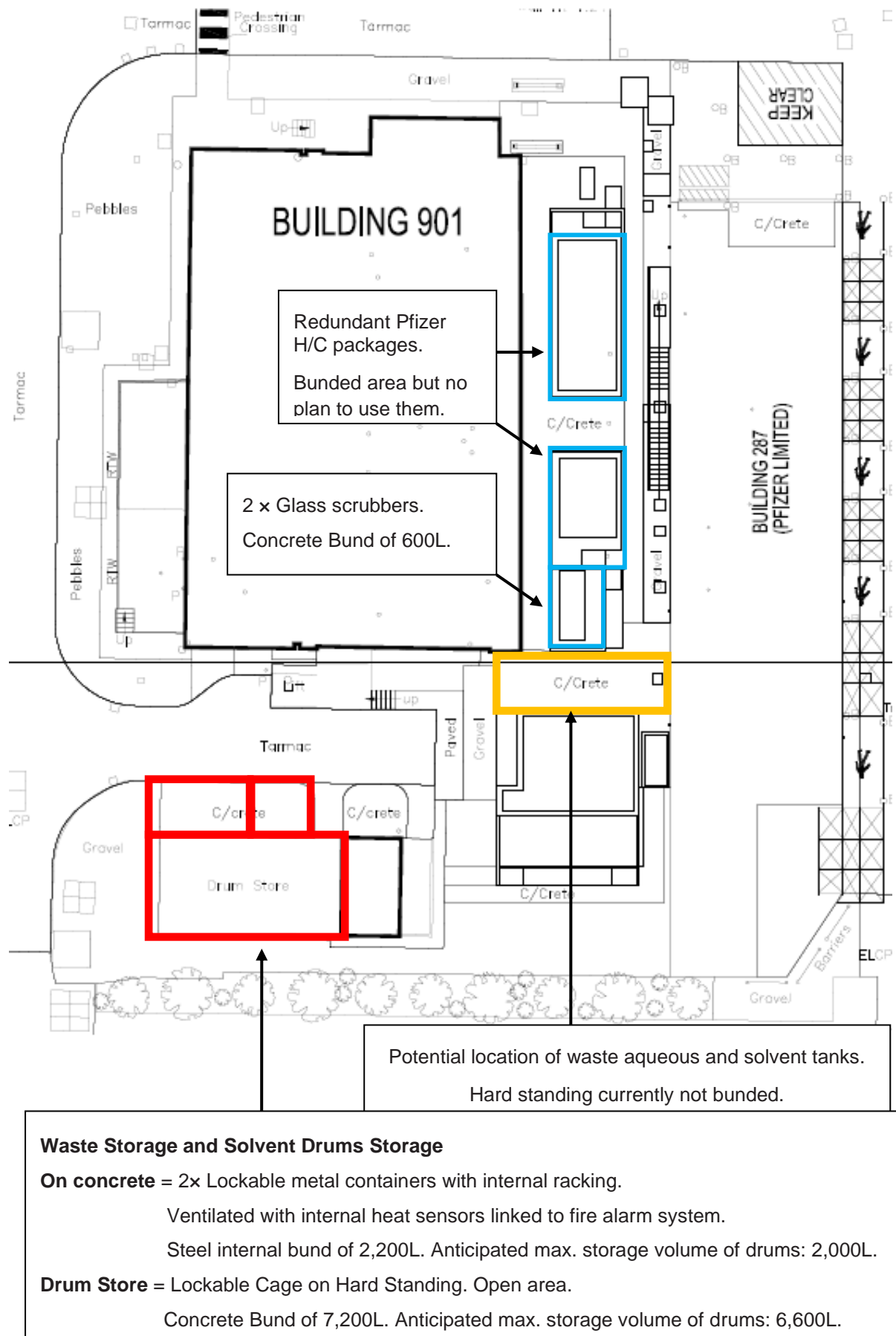


Figure 5-6: Breakdown of Internal Bund Locations and Volumes

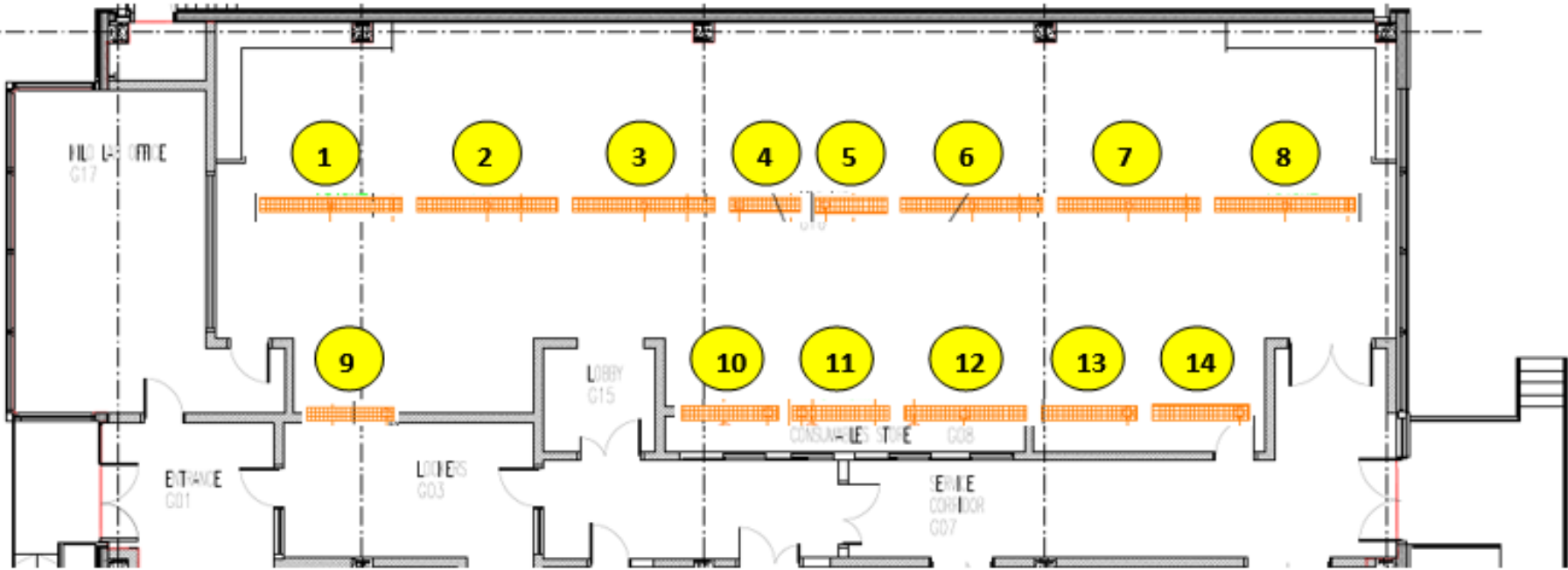


Table 5.3 Bund Details

| Bund Number | Bund Volume | Planned Fume Cupboard Occupancy | Equipment Volume |
|--------------------|--------------------|--|-------------------------|
| 1 | 120L | KL1 GLMS Reactor | 98l |
| 2 | 120L | KL2 GLMS Reactor | 105l |
| 3 | 120L | KL3 GLMS Reactor | 140L |
| 4 | 60L | Mobile equipment | NA |
| 5 | 60L | Mobile equipment | NA |
| 6 | 120L | Mobile equipment | NA |
| 7 | 120L | KL5 22 Reactor | 90L |
| 8 | 120L | KL6 C22 Reactor | 100L |
| 9 | 75L | future use | NA |
| 10 | 75L | future use | NA |
| 11 | 75L | future use | NA |
| 12 | 95L | Rotary Evaporator | 40L + 2x20L |
| 13 | 75L | Empty | NA |
| 14 | 75L | Empty | NA |

Assessment of Site-specific Pollution Risk

5.4.32 The assessment of site-specific pollution risk associated with each RHS identified for the CLS facility is summarised in Table 5.4.

Table 5.4: Assessment of Site-Specific Pollution Potential

| Relevant Hazardous Substance | Release Scenario | Receptor* | Mitigations / Pollution Prevention Measures / Risk Notes | Likelihood of Release | Likelihood of Receptor being Affected | Pollution Potential |
|------------------------------|--|---|---|-----------------------|---------------------------------------|---------------------|
| Diethyl ether | External spillage during delivery or removal as applicable when using the scissor lift, loss of primary containment as a result of an accident | Soils – Subsurface | All solvents are stored within bunded areas (self-bunded flammable storage container) on gridded spill trays. Management systems are in place for regular inspection, servicing and maintenance. Deliveries are overseen by trained staff. Spill kits are located around the site and emergency spill response procedures are in place at the site. Solvents are not stored in any containers greater than 25 L therefore impacts should a release occur will be minimal. | Unlikely | Unlikely | Low |
| Diethyl ketone | | Groundwater | | | | |
| Diisopropyl ether | | | | | | |
| Dioxane | | | | | | |
| Ethyl acetate | | | | | | |
| n-Heptane | | | | | | |
| n-Hexane | | | | | | |
| Methylene chloride | | | | | | |
| Tert-butyl methyl ether | | | | | | |
| Tetrahydrofuran | | | | | | |
| Toluene | | | | | | |
| m-xylene | | | | | | |
| Waste Solvents | External spillage during removal. | Soils – Subsurface | Inspection, pre-planned maintenance and management procedures All solvents are stored within bunded areas (self-bunded flammable storage container) on gridded spill trays. Management systems are in place for regular inspection, servicing and maintenance. Deliveries are overseen by trained staff. Spill kits are located around the site and emergency spill response procedures are in place at the site. | Unlikely | Unlikely | Low |
| | | Groundwater | | | | |
| Diethyl ether | Internal spillage during normal working activities | Immediate internal area / internal sealed | All solvents are stored within bunded areas. Operational areas are situated on impermeable areas and have a sealed drainage system. Spill kits are located around the site and emergency spill response procedures are in place at the site. | Unlikely | Unlikely | Low |
| Diethyl ketone | | | | | | |
| Diisopropyl ether | | | | | | |

| Relevant Hazardous Substance | Release Scenario | Receptor* | Mitigations / Pollution Prevention Measures / Risk Notes | Likelihood of Release | Likelihood of Receptor being Affected | Pollution Potential |
|------------------------------|------------------|-----------------|---|-----------------------|---------------------------------------|---------------------|
| Dioxane | | drainage system | Solvents are not stored in any containers greater than 25 L therefore impacts should a release occur will be minimal. | | | |
| Ethyl acetate | | | | | | |
| n-Heptane | | | | | | |
| n-Hexane | | | | | | |
| Methylene chloride | | | | | | |
| Tert-butyl methyl ether | | | | | | |
| Tetrahydrofuran | | | | | | |
| Toluene | | | | | | |
| m-xylene | | | | | | |

-
- 5.4.33 Operational production areas are all situated within the building on impermeable surfaces with bunded areas for storage of raw materials and sealed drainage system. External storage areas are situated on kerbed impermeable hardstanding areas and self-bunded containers are used for solvent storage, there is low potential for any RHS used or produced at the facility to affect any soils in landscaped areas.
- 5.4.34 The pathway to subsurface soils and groundwater underlying the operational facility is dependent on: the integrity / condition of either the surface hardstanding; the nature of any primary, secondary or tertiary containment measures included in design; and the operational / emergency measures implemented on the operational facility as part of its EMS and SOPs.
- 5.4.35 The location of storage raw materials and chemicals being within buildings and/or bunds with impermeable surfacing and sealed drainage will effectively limit their potential risk to groundwater and soil.
- 5.4.36 The site-specific pollution potential associated with the RHS has been determined as low.

6 STAGE 4 – PROVIDE A SITE HISTORY

6.1 Introduction

6.1.1 Stage 4 of the IED baseline assessment is to provide a site history

6.2 General Site History

Current Land Use

6.2.1 The site is located on Discovery Park which is a multi-business science park comprising laboratory, office and manufacturing facilities

6.2.2 The site was previously operated as a kilo laboratory production facility by Pfizer. The site was operated by Pfizer from 1998 until 2009. In June 2009, the facility was mothballed and decommissioned, no further production has taken place at the site since then and the building has been unoccupied. A copy of the Pfizer decommissioning report can be found in Appendix E.

Historical Land-use

6.2.3 The history of Discovery Park is summarised as follows:

- 1954 - Pfizer acquire 80-acre site at Sandwich as part of an expansion of its Kent-based activities.
- 1955 - Pfizer establish an animal-feed plant at the Sandwich site and enter the UK non-prescription market for the first time.
- 1957 - An agricultural division was opened at the Sandwich site.
- 1964 - Pfizer expands its Sandwich site, acquiring land for what would become known as the 'West site'.
- 1971 - Pfizer UK established 'Pfizer Central Research' with the mission to discover new pharmaceutical, chemical and agricultural products for Pfizer's worldwide operations.
- 1984 - A third phase of buildings was completed at the Sandwich site.
- 2011 - Pfizer renamed the Sandwich site 'Discovery Park' and put it on the market for sale.
- 2016 - Start of work on new on-site CHP renewable energy plant.

6.2.4 The history of the land within the current permit installation boundary is summarised as follows:

- Agricultural fields with land drain up to no earlier than 1908;
- By 1931, site occupied by military barracks;
- Between 1956 and 1975, site developed with industrial 'works' comprising Haffenden Rubber Moulding Company across the majority of the installation area. The Shuttlecock Works occupied the southern part of the land currently occupied by the Building 235 drum store;
- The site was developed by Pfizer as a pharmaceutical research and development pilot plant in the late 1990s; and
- The freehold to the Site and its surroundings was sold by Pfizer to Discovery Park Limited (DPL) in 2012.

6.2.5 Historic maps can be found in the Envirocheck report in Appendix C.

6.3 Surrounding Land-use

Current Overview

- 6.3.1 The CLS facility comprises a laboratory building and associated infrastructure which was last occupied and operated in 2009 by Pfizer. Since this date the site has been unoccupied.
- 6.3.2 Building 901 is surrounded on the western and eastern sides by Pfizer buildings. Building 287 to the east is used by Pfizer for the storage of 205 litre drums containing solvents and chemicals. This storage area is bunded.
- 6.3.3 The land uses surrounding the site comprise the following:
- North: Commercial and industrial buildings on the Discovery Park site. Building 287 used by Pfizer as a storage area.
 - East: A contractor's compound within the Discovery Park site. The area is used for storage of miscellaneous construction and maintenance materials. Beyond this is the River Stour.
 - South: Building 281 which is unoccupied. It was previously a manufacturing facility for Purogenix and was a warehouse for Pfizer storing similar products to that to be used by CLS.
 - West: Building 902 which is occupied by Pfizer and used for pharmaceutical products manufacturing.

6.4 Pollution History

Pollution Incidents

- 6.4.1 The Envirocheck report (Appendix C) details that there were four historic pollution incidents to controlled waters as shown in Table 6.1 below:

Table 6.1: Summary of Registered Permitted Sites

| Location | Pollutant | Distance from CLS | Notes | Incident Date | Incident Cause | Incident Severity |
|-----------------------------|--|-------------------|---|--------------------|-----------------------|-----------------------------------|
| Stonar Lake, Sandwich, Kent | Chemicals - Unknown | 81m – south west | Stones Around Lake Bleached White | 25th March 1993 | Industrial Chemicals | Category 3 – Minor Incident |
| Stonar Lake, Sandwich, Kent | Miscellaneous - Inert Suspended Solids | 175m – south east | Discharge into Stonar Lake | 10th October 1997 | Not Given | Category 3 – Minor Incident |
| Pfizers West Site | Organic Wastes: Other Suspended Solids | 484m – north west | Not Given | 1st September 1997 | Not Given | Category 2 - Significant Incident |
| Stonar Lake, Sandwich, Kent | Oils - Diesel (Including Agricultural) | 580m – south | Oils/Related Products Diesel Oil Film on Stonar Lake Now Dispersing | 5th July 1992 | Oils/Related Products | Category 3 – Minor Incident |

- 6.4.2 No pollution incidents have been directly attributed to the historic activities carried out in Building 901.

6.5 Potential for the Release of Hazardous Substances

6.5.1 The following have been identified as potential historical on-site sources of contamination:

- Manufacture of API by Pfizer including storage of raw materials and solvents.

6.5.2 The previous ground investigation as detailed below has identified some historic contamination which could be attributed to the previous operation at the site by Pfizer Limited. (see section 6.7)

6.6 Previous Ground Investigation

6.6.1 A baseline soil and groundwater investigation were undertaken in June 2014 to inform a permit application for Pfizer for building 902 which is adjacent to building 901. A copy of this report can be found in Appendix B. The findings of this investigation were as follows:

Ground Conditions

6.6.2 The ground conditions beneath the Site comprised:

- made ground to a maximum depth of 2.9m below ground level (bgl); overlying
- sandy/silty/clayey Tidal Flat Deposits (Unproductive Strata) to a maximum depth of >5m bgl; overlying
- sandy gravel Storm Beach Gravels (Secondary-A aquifer) proven to a maximum depth of >5m bgl.

6.6.3 Water strikes were encountered within the Tidal Flat Deposits at depths ranging between 2.9m and 4.0m bgl.

6.6.4 During the groundwater monitoring, resting water levels were recorded as 1.69m and 1.93m below the top of the well casing (btc) at PP_BH1 and PP_BH2 respectively. Groundwater contours could not be constructed from two monitoring wells, however the groundwater elevation at PP_BH2 was observed to be lower than at PP_BH1, consistent with an easterly component of groundwater flow.

6.6.5 No further ground investigations have been undertaken to inform this site condition report.

Baseline Soil and Groundwater Data

6.6.6 Six soil samples and two groundwater samples were collected, split between the two proposed installation boundary extension areas, in order to provide baseline data prior to Pfizer commencing operations in these areas.

6.6.7 In the western extension area, ammoniacal nitrogen was not reported above laboratory detection limit (LDL) in either of the two soil samples but was detected at a concentration of 4.07mg/l in the groundwater sample. The presence of ammoniacal nitrogen in groundwater in this area is considered to be due to historic regional impacts as described in URS report (June 2014)

6.7 Potential Historic Contaminants

6.7.1 In the eastern extension area, a number of analytes were reported in soil at concentrations exceeding the laboratory MDL, including:

- sodium, chloride, sulphate, polycyclic aromatic hydrocarbons (PAHs) (all four samples);
- Total petroleum hydrocarbons (TPH) (three of four samples); and
- carbazole, methyl alcohol and acetone (one of four samples).

6.7.2 The reported concentrations were considered to be typical of general made ground in an industrial setting and likely to be associated with historic land uses.

-
- 6.7.3 In the eastern extension area, a number of inorganic analytes were reported in groundwater at concentrations exceeding the laboratory MDL, including:
- sodium, chloride, sulphate; and
 - ammoniacal nitrogen.
- 6.7.4 The reported sodium, chloride and sulphate concentrations are considered to be consistent with their natural occurrence in the shallow groundwater in proximity to the tidal River Stour. The presence of ammoniacal nitrogen in groundwater in this area is considered to be due to historic regional impacts as described in the URS report (June 2014).
- 6.7.5 Bore holes 2 and 3 are proximate to B901 and would represent background data for the site.

Soil Data Summary

- 6.7.6 Four samples collected in the eastern extension area (PP_BH2, 0.4m; PP_BH2, 2.5m; PP_BH3, 0.3m and PP_BH3, 1.1m) were tested for the presence of chemicals of potential concern.
- 6.7.7 Sodium, chloride and sulphate were reported at concentrations above the LDL in all four samples. The soil pH was reported at values ranging between 8.14 and 11.53, indicating alkaline soil conditions. Ammoniacal nitrogen was reported above the LDL in both soil samples at PP2, with concentrations of 1.3mg/kg (0.4m bgl) and 4.4mg/kg (2.5m bgl) slightly exceeding the LDL of 0.6mg/kg. It is noted that the higher concentration was reported in the deeper sample, which was collected in soil close to the water strike.
- 6.7.8 Subsequent groundwater monitoring indicates the resting water level to be at approximately 2m bgl. The sample with a reported concentration of 4.4mg/kg is therefore from saturated soils and may be related to groundwater impacts (Section 4.4.3) rather than soil impacts at this point location.
- 6.7.9 TPH fractions were reported at concentrations above the LDL in three of the four samples. The maximum reported TPH concentration of 617mg/kg comprised primarily long chain aliphatic compounds (454mg/kg aliphatic C21-C35), with a smaller proportion of aromatic C21-C35 compounds (151mg/kg) and the remainder comprising aliphatic C16-C21 compounds (12mg/kg). TPH fractions with chain lengths less than C16 were not reported at concentrations above the LDL in any of the four samples.
- 6.7.10 PAH compounds were reported in all four samples at concentrations exceeding the LDL. The reported concentrations in the shallower samples at each location were higher than in the deeper samples.
- 6.7.11 Carbazole was reported at a concentration above the LDL in one of the four samples: PP_BH3 at 0.3m bgl. The reported concentration of 0.014mg/kg was marginally above the LDL of 0.010mg/kg.
- 6.7.12 One semi-volatile organic compounds (SVOC) tentatively identified compound (TIC) was reported in the sample collected at PP_BH2 at 2.5m bgl. The identified compound was octa-atomic sulphur, reported at a concentration of 0.419mg/kg.
- 6.7.13 Methyl alcohol and acetone were reported at concentrations above the laboratory MDL in one of the four samples; the shallow sample at PP_BH3 (0.3m bgl).
- 6.7.14 No other targeted compounds or TICs were reported in soil at concentrations above the laboratory LDLs.

Groundwater Data Summary

- 6.7.15 One sample collected in the eastern extension area (PP_BH2) was tested for the presence of chemicals of potential concern.
- 6.7.16 Sodium, sulphate, chloride and ammoniacal nitrogen were reported at concentrations above the laboratory MDL in the groundwater sample from PP_BH2. A groundwater pH of 7.63, indicating

approximately neutral groundwater conditions, was reported in the laboratory sample. Sodium, sulphate and chloride are considered to be natural constituents of the groundwater chemistry in the shallow groundwater environment in proximity to the tidal River Stour. The presence of ammoniacal nitrogen at a concentration above the LDL is considered to be due to historic regional impacts as described in URS report (June 2014).

- 6.7.17 Organic compounds, including Volatile organic compounds (VOCs), SVOCs, TPH, alcohols/acetates and glycols were not reported at concentrations above the LDL in the PP_BH2 groundwater sample.

6.8 Operational History

- 6.8.1 Building 901 was built in 1998 and up until 2009 was operated as a kilo manufacturing facility by Pfizer Limited in much the same way as is proposed by CLS for the operations at the facility.
- 6.8.2 Pfizer finished manufacturing in the facility in 2009, since this date the facility has been unoccupied and not used for any pharmaceutical manufacturing.
- 6.8.3 Building 901 is surrounded on the western and eastern sides by Pfizer buildings. Building 287 to the east is used by Pfizer for the storage of 205 litre drums containing solvents and chemicals. This storage area is bunded.
- 6.8.4 The land uses surrounding the site comprise the following:
- North: Commercial and industrial buildings on the Discovery Park site. Building 287 used by Pfizer as a storage area.
 - East: A contractor's compound within the Discovery Park site. The area is used for storage of miscellaneous construction and maintenance materials. Beyond this is the River Stour.
 - South: Building 281 which is unoccupied. It was previously a manufacturing facility for Purogenix and was a warehouse for Pfizer storing similar products to that to be used by CLS.
 - West: Building 902 which is occupied by Pfizer and used for pharmaceutical products manufacturing.

7 STAGE 5 – IDENTIFY THE SITE’S ENVIRONMENTAL SETTING

7.1 Introduction

7.1.1 Stage 5 of the IED baseline assessment is to identify the site’s environmental setting. A review of publicly available data has been undertaken to establish the environmental setting of the CLS installation.

7.2 Site Setting and Sources of Desk Study Information

7.2.1 The site is located on the Discovery Park industrial area in Sandwich, Kent.

7.2.2 The following information sources have been reviewed and provide information for this study:

- URS Baseline Soil and Groundwater Investigation (June 2014) – Appendix B
- Envirocheck Report (Landmark Information Group, December 2019) - Appendix C
- Pfizer Building 901 Decommissioning Report (2009) – Appendix E
- Environment Agency Pre Application Nature and Heritage Conservation Screening Report – Appendix F
- Magic Map⁴
- British Geological Survey, Geology of Britain Viewer⁵

7.3 Topography

7.3.1 Building 901 is located on a flat area of land at an elevation of approximately 4.9m. The Discovery Park site itself lies at an elevation ranging from approximately 1.2m to 6.7m.

7.4 Geology

7.4.1 BGS on-line mapping indicates that the Site is underlain by Tidal Flat deposits of clay and silt. In turn, this is underlain by Thanet Formation, comprising sand, silt and clay.

7.4.2 The ground investigation carried out in 2014 indicated a general geological sequence beneath the site of:

- Made Ground;
- Clayey alluvium to approximately 5m bgl;
- Sandy alluvium to approximately 15m bgl;
- Sand and gravel (alluvium) to approximately 20m bgl;
- Thanet Formation (very dense clayey sand/sandy clay) to approximately 22m bgl;
- Bullhead Beds (gravel and cobble of flint to approximately 23 m bgl; and
- Upper Chalk.

⁴ <https://magic.defra.gov.uk/MagicMap.aspx>

⁵ <http://mapapps.bgs.ac.uk/geologyofbritain/home.html>

7.5 Hydrogeology

- 7.5.1 The Tidal Flat deposits immediately underlying the site (clayey, sandy alluvium described above) are classified as Unproductive Strata.
- 7.5.2 The sand and gravel alluvium described above is likely to represent the Storm Beach Deposits, which are classified as a Secondary-A aquifer. The underlying Thanet Formation is classified as a Secondary-A aquifer, with the Upper Chalk classified as a Principal aquifer.
- 7.5.3 The site does not lie within any groundwater source protection zones.
- 7.5.4 Historic site investigation carried in 2014 indicates that the shallow groundwater flow direction within the alluvium is likely to be in a generally south-easterly direction towards North Lake and the River Stour.

7.6 Hydrology

- 7.6.1 The River Stour is located approximately 50 m to the east of the Site, with North Lake located approximately 170m to the south.

7.7 Man-made Pathways

- 7.7.1 A drainage plan of the external areas of the site can be found in Appendix A. Surface water drainage in external areas drains to the Discovery Park WWTP.

7.8 Environmental Consents, Licenses, Authorisations, Permits and Designations for the Site and Surrounding Areas

Water Discharges and Abstraction Licenses

- 7.8.1 There are no discharge consents associated with the facility. There are a number of active discharge consents within 500m of the site as shown in Table 7.1 below.
- 7.8.2 There are a number of water abstraction licences within 1 km of the Site as shown in Table 7.2 below.

Table 7.1: Discharge Consents

| Address & permit number | Distance from the CLS installation | Discharge Type | Receiving Water Body | Comments |
|--|------------------------------------|---|--------------------------------------|--|
| Pfizer Limited, Release Point W4, Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ | 111m – north east | Discharge of Other Matter - Surface Water | Saline Estuary River Stour & Minster | Issue Date - 19th May 2000 |
| Pfizer Ltd, Building 530, East Site, Ramsgate Rd, Sandwich, Kent, Ct13 | 170m – south | Trade Discharge - Process Water | Lake/Reservoir - with outlet | Issue Date – 17 th December 2001 Revocation Date – 26 th April 2002 |
| Pfizer Limited, Release Point W4, Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ | 228m – north east | Trade Effluent | Saline Estuary | Issue Date – 17 th May 1996 Revocation Date – 19 th May 2000 |
| PGRD - Pfizer Ltd West Site Development at Pfizer Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ | 293m – west | Trade Discharge - Process Water | Saline Estuary River Stour & Minster | Issue Date – 7 th November 2003 Revocation Date – 24 th July 2005 |
| Pfizer Ltd., Richborough Works, Sandwich, Kent | 309m – north east | Trade Discharges - Cooling Water | Saline Estuary Old-Great Sour | Issue Date – 19th March 1985 Revocation Date – 5th June 1996 |
| Pfizer Limited, Release Point W4, Pfizer Ltd, Ramsgate Road, Sandwich, Kent, Ct13 9nj | 313m – east | Trade Discharges - Cooling Water | Saline Estuary Old-Great Sour | Issue Date – 17 th May 1996 Revocation Date – 19 th May 2000 |
| Pfizer Ltd. Release Point W4, Pfizer Ltd, Ramsgate Road, Sandwich, Kent, Ct13 9nj | 332m – east | Trade Effluent | Saline Estuary | Issue Date – 17 th May 1996 Revocation Date – 19 th May 2000 |
| PGRD - Pfizer Ltd, West Site Development at Pfizer Pfizer Ltd, Ramsgate Road, Sandwich, Kent, Ct13 9nj | 418 – south west | Trade Discharge - Process Water | Tributary of River Stour | Issue Date – 28 th June 1989 Revocation Date – 31 st March 2007 |

| Address & permit number | Distance from the CLS installation | Discharge Type | Receiving Water Body | Comments |
|--|------------------------------------|---------------------------------|--------------------------|--|
| PGRD - Pfizer Ltd, West Site Development at Pfizer Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ | 398 – south west | Trade Discharge - Process Water | Tributary of River Stour | Issue Date - 19th January 2000 Revocation Date - 27th June 2002 |

Table 7.2: Water abstractions

| Address & permit number | Licence Number | Distance from the CLS installation | Abstraction | Comments |
|--|-----------------|------------------------------------|---------------|--|
| Pfizer Limited, Sandwich | 4/0166/GR | 105m – south east | Groundwater | - |
| Jackson Civil Engineering Limited Catchpit 2 Sandwich | So/040/0013/005 | 585m – east | Groundwater | Permit Start Date – 14 th June 2013 |
| Mrs Miriam Bull, Town Clerk | 9/195 | 943m – south west | Surface Water | - |
| Jackson Civil Engineering Limited Catchpit 1 Sandwich | | 984m – north east | Groundwater | Permit Start Date – 14 th June 2013 |

Landfill Sites

7.8.3 Historic landfills situated within 1km of the installation can be found in Table 7.3 below

Table 7.3: Summary of registered historical and active landfill sites

| Distance from the Proposed Site | Location & License Holder | Status | Waste Type |
|---------------------------------|---|------------------------------|---|
| Historical landfills | | | |
| 77 m (SE) (on Site) | Haffenden - Richborough Limited Ramsgate Road | Last input date not supplied | Deposited Waste included Industrial Waste |
| 857 m (NW) | Old CEGB Site at Richborough Manston Road, Margate, Kent | 31st December 1990 | Deposited Waste included Commercial and Household Waste |

Permitted Sites

7.8.4 The following tables contain information taken from the Environment Agency public register⁶ and the Envirocheck Landmark report obtained for the CLS installation and summarises both historical and registered installations and waste facility applications, made to the EA located within 1 km of the installation.

7.8.5 Table 7.4 below includes details of the status of each facility (Active, Superseded, Revoked, Modification, Variation, Transfer or Not yet authorised).

7.8.6 Distances given in this table are measured from the centre of the CLS installation.

⁶ https://environment.data.gov.uk/public-register/api/search?_postcode=CT13+9ND&dist=1&easting=633428&northing=159463

Table 7.4: Summary of Registered Permitted Sites

| Permit Holder | Address | Process | Licence Reference | Status | Distance from the Proposed Site |
|--------------------------------------|---|---|-------------------|--|---------------------------------|
| York Bioanalytical Solutions Limited | Building 530, Discovery Park, Ramsgate Road, Sandwich, CT13 9ND | Keeping & Use of Radioactive Materials and Disposal of Radioactive Waste (F) | DB3235DP | Approval Date – 1 st April 2018 | 236m – south west |
| Pfizer R&D UK Limited | Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND | Pharmaceuticals; Producing Pharmaceuticals Using Chemical/Biological Processes | RP3734QE | Permission Date – 21 st November 2019 | 57m – south west |
| Purogenix Limited | Purogenix Ltd, Old Bay House, River Road, Discovery Park, Sandwich, Kent, CT13 9FN | Pharmaceuticals; producing pharmaceuticals using chemical/biological processes Associated process | GP3334RY | Permission Date – 16 th November 2017 | 147m – south |
| Kent Renewable Energy Limited | Discovery Park, off Ramsgate Road, Sandwich, Kent | Combustion; any fuel =>50mw | LP3034RD | Permission Date – 30 th January 2018 | 300m - north |
| BWSC Generation Services UK Ltd | Discovery Park, off Ramsgate Road, Sandwich, Kent | Combustion; any fuel =>50mw | MP3304PJ | Permission Date – 8 th August 2019 | 300m - north |
| WasteCare Limited | WasteCare East Kent, Discovery Park, Ramsgate Road, Sandwich, CT13 9FN | Keeping & Use of Radioactive Materials and Disposal of Radioactive Waste (H) | LB3691DN | Approval Date – 10 th June 2019 | 290m – north east |
| Discovery Park Management Limited | Pfizer Global Manufacturing, Sandwich Pharmaceuticals Plant, Ramsgate Road, Kent, CT13 9NJ | Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving biological treatment Other waste disposal; non-hazardous waste >50t/d by biological treatment Pharmaceuticals; producing pharmaceuticals using chemical/biological processes Other waste disposal; hazardous waste >10t/d Combustion; any fuel =>50mw Other waste disposal; non-hazardous waste >50t/d by physico-chemical treatment | AP3438YK | Permission Date – 3 rd May 2017 | 445m - north |

| Permit Holder | Address | Process | Licence Reference | Status | Distance from the Proposed Site |
|-------------------|--|---|--|--|---------------------------------|
| | | The incineration of hazardous waste in an incineration or co-incineration plant with a capacity exceeding 10 tonnes per day | | | |
| Pfizer Limited | Pfizer Global Manufacturing, Sandwich Pharmaceuticals Plant, Ramsgate Road, Kent, CT13 9NJ | Other waste disposal; non-hazardous waste >50t/d by biological treatment Incineration of hazardous waste Pharmaceuticals; producing pharmaceuticals using chemical/biological processes Other waste disposal; hazardous waste >10t/d Combustion; any fuel =>50mw Other waste disposal; non-hazardous waste >50t/d by physico-chemical treatment | HP3539LX | Permission Date – 16 th June 2011 | 422m - north |
| WasteCare Limited | East Kent Waste Recovery Facility, Ramsgate Road, Kent, CT13 9ND | Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving physico-chemical treatment Temporary storage of haz waste not under s 5.2 pending activities listed in s 5.1, 5.2, 5.3 and paragraph (b) of this section with a total capacity > 50 tonnes, excl temp storage where generated The incineration of hazardous waste in an incineration or co-incineration plant with a capacity exceeding 10 tonnes per day Associated process | TP3200PR | Permission Date – 8 th May 2019 | 422m - north |
| WasteCare Limited | East Kent Waste Recovery Facility, Ramsgate Road, Sandwich, Kent, CT13 9NJ | A13: Household Waste Amenity Site | Permit number - TP3200PR/T 001 Waste Management Licence Number - 405826 | Effective Date – 11 th May 2019 | 422m - north |

| Permit Holder | Address | Process | Licence Reference | Status | Distance from the Proposed Site |
|-----------------------|--|--|--|---|---------------------------------|
| Valeside Services Ltd | Unit B3, The Boat Yard, Sandwich Industrial Estate, Sandwich, Kent, CT13 9LY | A19: Metal Recycling Site (Vehicle Dismantler) | Permit number - GB3407TP/A 001 Waste Management Licence Number - 405010 | Issued Date – 5 th April 2019 | 965m – south east |
| Copart UK Limited | Land/ Premises At, Ramsgate Road, Sandwich, Kent, CT13 9ND | A19: Metal Recycling Site (Vehicle Dismantler) | TP3995HD/V 002 | Issued – 10 th July 2001 Last Modified – 2 nd March 2012 | 787m - north |
| Universal Salvage Plc | Universal Salvage Auction Site, Ramsgate Road, Sandwich, Kent, CT13 9NB | Scrapyard | Waste Management Licence Number - 10020 | Dated - 10 th July 2001 | 923m – north |
| Richborough Landfill | Rear of Richborough Civic Amenity Site, Ramsgate Road, Richborough, Sandwich, Kent, CT13 9NW | Household, Commercial and Industrial Waste Landfills | Waste Management Licence Number - 19612 | Issued - 25 th February 1985 | 807m – north west |

Statutory Designated Sites within 10km

7.8.7 Statutory designation sites within a 10km search radius around the CLS installation boundary are summarised in Table 7.5 below:

Table 7.5: Statutory Designated Sites

| Site Name | Designation | Distance from the CLS Site |
|---|---|----------------------------|
| Sandwich Bay | Special Areas of Conservation (SAC) | 0.07km – north east |
| Thanet Coast & Sandwich Bay | Special Protection Areas (SPA) | 0.07km – north east |
| Thanet Coast & Sandwich Bay | Ramsar | 0.07km – north east |
| Sandwich Bay to Hacklinge Marshes | Sites of Special Scientific Interest (SSSI) | 0.07km – north east |
| Ash Level and South Richborough Pasture | Local Wildlife Sites (LWS) | 0.59km – north west |
| Sandwich & Pegwell Bay | National Nature Reserve (NNR) | 1.98km - east |
| Thanet Coast | Special Areas of Conservation (SAC) | 4.54km – north east |
| Stodmarsh | Special Areas of Conservation (SAC) | 9.89km – north west |

Mining

7.8.8 The site has been identified as being in an area which may be affected by coal mining activity. As there is no additional construction or changes to the site layout proposed, a coal mining report has not been obtained from the Coal Authority to inform this report.

COMAH and Hazardous Substance Consents

7.8.9 Details of COMAH sites and sites with Planning Hazardous Substance Consents within the locality can be found in Table 7.6 and 7.7 below.

Table 7.6: COMAH and Hazardous Substance Consents

| Site Name | Location | Type | Distance from the CLS Site |
|--------------------------|---|------------|----------------------------|
| Pfizer Ltd | Research and Manufacture, Ramsgate Road, Sandwich, Kent, CT13 9NJ | Lower Tier | 122m – north west |
| Augean Treatment Limited | Ramsgate Road, Sandwich, Kent, CT13 9ND | Lower Tier | 272m – north east |

Table 7.7: Planning Hazardous Substance Consents

| Site Name | Location | Application Reference / Hazardous Substance | Distance from the CLS Site |
|------------|-----------------------------------|---|----------------------------|
| Pfizer Ltd | Ramsgate Road, Sandwich, CT13 9NJ | CD8015/CD8015 Toxic | 248m – west |

| Site Name | Location | Application Reference / Hazardous Substance | Distance from the CLS Site |
|-----------------------------------|---|---|----------------------------|
| Pfizers Ltd | Ramsgate Road, SANDWICH, Kent, CT13 9NJ | /00/00054/ Combination of Dangerous Substances | 261m - west |
| East Kent Waste Recovery Facility | East Kent Waste Recovery Facility, Discovery Park, Sandwich, CT13 9FN | 14/00437 Combination of Dangerous Substances | 368m – north east |
| Augean Treatment Limited | East Kent Waste Recovery Facility, River Road, Discovery Park, Sandwich, CT13 9FN | 13/00673 Combination of Dangerous Substances | 414m – north east |

Radon

- 7.8.10 The site is identified to be located in a lower probability radon area (less than 1% of homes are estimated to be at or above the action level).

8 STAGE 6 – SITE CHARACTERISATION

8.1 Introduction

8.1.1 Stage 6 of the IED baseline assessment is to characterise the site. The following sections provide a summary of the potential contamination sources, pathways and receptors identified at the CLS site, based on the reports identified in Section 7.2.

8.2 Potential Contamination Sources

8.2.1 Based on the historical site information, ground investigation and monitoring undertaken by URS, the following potential contamination sources at the CLS site were identified:

- On-site:
 - Chemical contamination associated with the historic on-site uses including storage of raw materials, solvents and wastes associated with the previous site occupancy by Pfizer.
- Off-site
 - Chemical contamination associated with the adjacent Discovery Park tenants (inorganic, organic contamination).

8.3 Identified Receptors

8.3.1 The following key receptors that may be at risk from contamination in soils and groundwater beneath the CLS installation were identified as:

- Human Health
 - Future site users;
- Controlled Waters
 - Groundwater within the Tidal Flat Deposits (Superficial Aquifer - Unproductive Strata)
 - Groundwater within the Storm Beach deposits (Bedrock Aquifer - Secondary A Aquifer);
 - Groundwater within the Thanet Sand Formation (Secondary-A aquifer); and
 - Groundwater within the Upper Chalk (Principal aquifer).
 - Surface Water: River Stour and North Lake

8.4 Pathways

8.4.1 The following potential contamination pathways were identified at the CLS installation, particularly in areas that are not paved or covered by hardstanding:

- Human Health
 - Potential impact to human health via direct dermal contact, ingestion (dust and / or soils) and inhalation (dust / vapours) with soil and groundwater contaminants;
 - Indoor and Outdoor inhalation of vapours of contaminants of concern.
- Controlled Waters
 - Potential migration of dissolved phase soil contamination vertically into groundwater;
 - Potential migration of dissolved phase contamination from groundwater underlying the CLS site to local surface water courses (River Stour and North Lake)

8.4.2 The risk assessment is based on a future industrial use of the Site and presented in Table 5.1 and Table 5.2.

Table 8.1: Conceptual Site Model – Human Health Receptors

| Source | Pathway | Receptor | Risk | Notes |
|--|--|-------------------|------|--|
| HUMAN HEALTH RECEPTORS | | | | |
| On-site Chemical contamination in Made Ground as consequence of current / historical site activities | Ingestion and dermal contact of soil / dust and Inhalation of organic vapours and/or asbestos fibres | Future Site Users | Low | <p>URS ground investigation has identified suspected asbestos cement fragments were observed at a depth of 1.1m bgl during hand excavation at PP_BH3A.</p> <p>Soil pH was reported as showing alkaline conditions (pH8.14 – 11.53). TPH fractions were reported at concentrations above the laboratory detection limit (LDL) in three of the four samples.</p> <p>PAH compounds were reported in all four samples at concentrations exceeding the LDL.</p> <p>Carbazole was reported at a concentration above the LDL in one of the four samples (PP_BH3).</p> <p>Methyl alcohol and acetone were reported at concentrations above the LDL in one of the four samples (PP_BH3)</p> <p>The reported concentrations were considered to be typical of general made ground in an industrial setting and likely to be associated with historic land uses.</p> <p>Further risk assessments should be undertaken prior to any construction work or changes to site layout. No immediate health and safety risks to human health have been identified in the context of the current or proposed use of the site.</p> |

Table 8.2: Conceptual Site Model – Controlled Water Receptor

| Source | Pathway | Receptor | Risk | Notes |
|--|---|-------------|------|---|
| CONTROLLED WATER RECEPTORS | | | | |
| Chemical contamination in Made Ground as consequence of current / historical site activities | Leaching of soil contamination and vertical migration | Groundwater | Low | <p>In the eastern extension area, a number of inorganic analytes were reported in groundwater at concentrations exceeding the LDL, including:</p> <ul style="list-style-type: none"> • sodium, chloride, sulphate; and • ammoniacal nitrogen. <p>The reported sodium, chloride and sulphate concentrations are considered to be consistent with their natural occurrence in the shallow groundwater in proximity to the tidal River Stour.</p> <p>The presence of ammoniacal nitrogen in groundwater in this area is considered to be due to historic regional impacts.</p> |
| | | | Low | <p>Additionally, the CLS installation is not located within a Source Protection Zone and there are no groundwater abstractions within the vicinity of the CLS installation. The risk to controlled water is therefore deemed to be low.</p> |

9 STAGE 7 – SITE INVESTIGATION

- 9.1.1 Stage 7 of the IED baseline assessment is to carry out a site investigation to obtain additional information where only part of the site can be characterised or there is insufficient information on which to formulate a baseline report.
- 9.1.2 The following ground investigation was carried out in the vicinity of the CLS facility:
- URS, Baseline Soil and Groundwater Investigation (June 2014) (Appendix B)
- 9.1.3 It has been identified that the facility (Building 901) has been unoccupied since 2009. It is therefore considered that the ground investigation in June 2014 is therefore representative for a baseline of the site and no further ground investigations have been undertaken to inform this report. All RHSs have been listed in the URS report (June 2014) as being used and stored at the site and considered within the analysis suite for testing.
- 9.1.4 The report detailing the historical ground investigations undertaken by URS in 2014 was made available by CLS. This report presented the findings of ground investigations undertaken across the wider site. The locations of the ground investigations are shown in Figure 2 of the Baseline Soil and Groundwater Investigation in Appendix B of this report.
- 9.1.5 The ground investigations and the exploratory borehole logs identified that site-specific ground conditions across the wider site comprise the following units (URS, 2014):
- Made Ground - was encountered in borehole PP_BH1 to depths of between 1.4 – 2.9 m bgl and consisted of brown gravelly sand with gravel of red brick, concrete and flint and cobble of concrete.
 - Natural Ground: Superficial deposits – Tidal Flat Deposits consisting of orange/red/brown mottled clay, becoming silty/sandy from approximately 2.5m bgl. Olive fine to medium sand from 2.9m at PP_BH2.
 - Natural Ground: Bedrock – Storm Beach Gravels consisting of brown sandy gravel. Fine to coarse sand and fine to medium sub-rounded flint gravel encountered at 4.5 to >5 m bgl.
- 9.1.6 URS undertook intrusive ground investigation works in the vicinity of the CLS site in May 2014. The exploratory borehole logs have allowed the specific ground conditions in the vicinity of the CLS site to be established. The investigation works comprised:
- five boreholes designated PP_BH1, PP_BH1A, PP_BH2, PP_BH3 and PP_BH3A were drilled to depths of 5.00m below ground level using Dynamic Sampling Terrier Drilling Rig;
- 9.1.7 Concrete hardstanding at borehole locations PP_BH2 and PP_BH3 was cored using a diamond drill at 300mm diameter. Hand excavated starter boreholes were dug at all three locations to a depth of 1.2m below ground level (bgl).
- 9.1.8 Suspected asbestos cement fragments were encountered at a depth of 1.1m bgl at location PP_BH3 in the first-hand excavated borehole. In accordance with health and safety protocols, this location was terminated and backfilled. This sampling location was re-labelled PP_BH3A for soil sample purposes. A second-hand excavated borehole was dug approximately 1m to the east of PP_BH3A and no suspected asbestos was encountered. This second location, labelled PP_BH3, was used for the subsequent drilling and well installation.
- 9.1.9 Boreholes were advanced at the three locations using a 100mm diameter dynamic window sampling drilling method to a maximum depth of 5m bgl. A refusal was encountered on a suspected concrete obstruction at a depth of 1.5m bgl at location PP_BH1. This sampling location was re-labelled PP_BH1A for soil sample purposes. A second location was advanced approximately 1m to the north of PP_BH1A and no refusal was encountered. This second location, labelled PP_BH1, was used for the subsequent drilling and well installation.

9.1.10 As planned, 50mm diameter high-density polyethylene (HDPE) construction monitoring standpipes were installed in two of the three boreholes, PP_BH1 and PP_BH2. The third borehole, PP_BH3, was backfilled with soil arisings and reinstated at the surface with concrete.

9.1.11 A summary of the drilled depths and well installation details for each borehole is shown in Table 9.1 below.

Table 9.1: Summary of Borehole Depths and Well Installation Details

| Location | Borehole Depth | Response Zone |
|----------|----------------|---|
| PP_BH1A | 1.5m | No well installed |
| PP_BH1 | 5.0m | Alluvium |
| PP_BH2 | 5.0m | Natural deposits, Lambeth Group (2 to 6m bgl) |
| PP_BH3A | 1.1m | No well installed |
| PP_BH3 | 5.0m | Natural deposits, Lambeth Group (1.5 to 3.5m bgl) |

9.1.12 Table 9.2 summarises the encountered ground conditions. The exploratory hole logs are included in the URS report (URS, 2014), included within Appendix B.

Table 9.2: Geological Summary

| Stratum | General Description | Top of strata (mBGL) | Base of strata (mBGL) | Thickness Range (m) |
|---------------------|---|----------------------|-----------------------|---------------------|
| Made Ground | At PP_BH1, brown gravelly sand with gravel of red brick, concrete and flint and cobble of concrete. | Ground surface | 1.4 to 2.9 | 1.4 to 2.9 |
| Tidal Flat Deposits | Orange/red/brown mottled clay, becoming silty/sandy from approximately 2.5m bgl. Olive fine to medium sand from 2.9m at PP_BH2. | 1.4 to 2.9 | 4.5 to >5 | 1.6 to > 3.35 |
| Storm Beach Gravels | Brown sandy gravel. Fine to coarse sand and fined to medium sub-rounded flint gravel. | 4.5 to >5 | >5 | >0.5 |

9.1.13 Details of the groundwater samples can be found in Table 9.3 below:

Table 9.3: Summary of Groundwater Levels

| Monitoring Well | Screened Unit | Depth to Groundwater (mBGL) Strike during drilling | Depth to Groundwater (mBGL) Resting | Groundwater Elevation (mAOD) |
|-----------------|---------------------|--|-------------------------------------|------------------------------|
| PP_BH1 | Tidal Flat Deposits | 4.0 | 1.69 | 0.69 |
| PP_BH2 | Tidal Flat Deposits | 2.9 | 1.93 | 0.24 |
| PP_BH3 | None | 3.2 | n/a | n/a |

9.1.14 The soil and groundwater samples collected during these intrusive ground investigations were subjected to a suite of analyses that included the following:

- Sodium;
- TPH with aliphatic/aromatic split;
- VOCs & TICs;
- SVOCs & TICs;
- Glycols;
- Alcohols and acetates;
- Ammoniacal nitrogen;
- Sulphate;
- Chloride; and
- pH

9.1.15 This general suite reflects the historical operations undertaken on or near the CLS installation. The analytical suite, includes the majority of RHS identified however the chemicals listed below are not included in the URS investigation analysis suite therefore a baseline concentration cannot be provided:

- Diethyl ether
- Diethyl ketone
- Diisopropyl ether
- Dioxane
- n-Heptane
- n-Hexane
- Tert-butyl methyl ether

9.1.16 Soil and groundwater analysis are to be used to inform the baseline of the soil and groundwater underlying the CLS facility.

10 STAGE 8 – PRODUCE A BASELINE REPORT

10.1 Introduction

- 10.1.1 Stage 8 of the IED baseline assessment is to summarise all of the information collected in stages 1 to 7 to produce a report which identifies the state of the soil and groundwater contamination by relevant hazardous substances.
- 10.1.2 The following section summarises the laboratory chemical analysis undertaken on soil samples collected by URS following completion of their ground investigation in May 2014 (URS, 2014) (Appendix B of this report), and groundwater samples collected by URS in 2014 (Appendix B of this report).
- 10.1.3 The analytical dataset presented in this section defines the general baseline soil quality (principally Made Ground) and the general baseline groundwater quality across the CLS installation.

10.2 Baseline Soil Quality

- 10.2.1 Soil samples collected as part of the site investigation as detailed in the URS report (URS, 2014) in Appendix B, were sent for analysis for the presence of a selection of potential contaminants taking into account the potential contaminant sources in the area.
- 10.2.2 The analytical schedule was based on the inventory of chemical drums that were expected to be used and stored by the Pfizer operation. Further details of the analysis suite can be found in Section 9.1.14 above.
- 10.2.3 The results of the soil analysis have been compared with against the Suitable 4 Use Levels (S4ULs) that have been derived by Land Quality Management Ltd (LQM, 2015)⁷ using the Contaminated Land Exposure Assessment (CLEA) framework. Contaminant concentrations below the respective S4UL criteria represent a tolerable or minimal risk level to human health as described in the EA's SR2 Report (EA, 2009)⁸. Details of the generic assessment criteria (GACs) can be found in Appendix G.
- 10.2.4 S4ULs have been adopted with the exception of lead, where no S4UL is available and the Category 4 Screening Levels (C4SLs), developed by CL:AIRE for a limited number of contaminants and first published in 2014, have been used instead (CL:AIRE, 2014)⁹
- 10.2.5 In the absence of S4ULs and C4SLs, Generic Assessment Criteria (GAC) developed by CL:AIRE (CL:AIRE, 2010)¹⁰, have been used as a screening tool to indicate whether levels of contaminants may pose a risk to human health.
- 10.2.6 Where contaminant concentrations are above S4UL / C4SL criteria, further risk assessment and possibly remediation may be required.
- 10.2.7 This section utilises soil analysis data derived from the ground investigation undertaken by URS in 2014 near to the CLS installation and compares them against appropriate screening criteria for a commercial end use.
- 10.2.8 The Tables below provide a summary and comparison of the soil analytical results. Full laboratory analysis reports are included within the URS report in Appendix B of this report.

⁷ <https://www.lqm.co.uk/publications/s4ul/>

⁸ <https://www.gov.uk/government/publications/human-health-toxicological-assessment-of-contaminants-in-soil>

⁹ <https://www.claire.co.uk/projects-and-initiatives/category-4-screening-levels>

¹⁰ <https://www.claire.co.uk/component/phocadownload/category/8-initiatives?download=44:gac-report-6-12-09b>

Table 10.1: Summary of Soil Analytical Results (Boreholes PP_BH2 & PP_BH3)

| Determinand | S4ULs (mg/kg) | EIC/AGS/CL:AIRE (mg/kg) | Laboratory Limit of Detection | PP_BH2 | PP_BH2 | PP_BH3 | PP_BH3 |
|------------------------------|---------------|-------------------------|-------------------------------|--------|--------|--------|--------|
| >C10-C12 | 3200 (340) | - | <0.2 mg/kg | <0.2 | <0.2 | <0.2 | <0.2 |
| >C12-C16 | 59000 (24) | - | <4 mg/kg | <4 | <4 | <4 | <4 |
| >C16-C21 | 1600000 | - | <7 mg/kg | <7 | <7 | 12 | <7 |
| >C21-C35 | 1600000 | - | <7 mg/kg | 42 | <7 | 454 | <7 |
| >C5-C6 | 26000 (1220) | - | <0.1 mg/kg | <0.1 | <0.1 | <0.1 | <0.1 |
| >C5-EC7 | 26000 (1220) | - | <0.1 mg/kg | <0.1 | <0.1 | <0.1 | <0.1 |
| >C6-C8 | 56000 (869) | - | <0.1 mg/kg | <0.1 | <0.1 | <0.1 | <0.1 |
| >C8-C10 | 3500 (613) | - | <0.1 mg/kg | <0.1 | <0.1 | <0.1 | <0.1 |
| >EC10-EC12 | 16000 (364) | - | <0.2 mg/kg | <0.2 | <0.2 | <0.2 | <0.2 |
| >EC12-EC16 | 36000 (169) | - | <4 mg/kg | <4 | <4 | <4 | <4 |
| >EC16-EC21 | 28000 | - | <7 mg/kg | <7 | <7 | <7 | <7 |
| >EC21-EC35 | 28000 | - | <7 mg/kg | 157 | 80 | 151 | <7 |
| >EC7-EC8 | 56000 (869) | - | <0.1 mg/kg | <0.1 | <0.1 | <0.1 | <0.1 |
| >EC8-EC10 | 3500 (613) | - | <0.1 mg/kg | <0.1 | <0.1 | <0.1 | <0.1 |
| 1,1,1,2-Tetrachloroethane | 110 | - | <5 µg/kg | <5 | <5 | <5 | <5 |
| 1,1,1-Trichloroethane | 660 | - | <5 µg/kg | <5 | <5 | <5 | <5 |
| 1,1,2,2-Tetrachloroethane | 270 | - | <3 µg/kg | <3 | <3 | <3 | <3 |
| 1,1,2-Trichloroethane | | 94 | <4 µg/kg | <4 | <4 | <4 | <4 |
| 1,1-Dichloroethane | | 280 | <6 µg/kg | <6 | <6 | <6 | <6 |
| 1,1-Dichloroethene (1,1 DCE) | | 26 | <6 µg/kg | <6 | <6 | <6 | <6 |
| 1,2,3-Trichlorobenzene | 102 | - | <7 µg/kg | <7 | <7 | <7 | <7 |

| Determinand | S4ULs (mg/kg) | EIC/AGS/CL:AIRE (mg/kg) | Laboratory Limit of Detection | PP_BH2 | PP_BH2 | PP_BH3 | PP_BH3 |
|------------------------|---------------|-------------------------|-------------------------------|--------|--------|--------|--------|
| 1,2,4-Trichlorobenzene | 220 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| 1,2,4-Trichlorobenzene | 220 | - | <7 µg/kg | <7 | <7 | <7 | <7 |
| 1,2,4-Trimethylbenzene | | 42 | <6 µg/kg | <6 | <6 | <6 | <6 |
| 1,2-Dichlorobenzene | 2000 (571) | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| 1,2-Dichloroethane | 0.67 | - | <5 µg/kg | <5 | <5 | <5 | <5 |
| 1,2-Dichloropropane | | 3.3 | <4 µg/kg | <4 | <4 | <4 | <4 |
| 1,3-Dichlorobenzene | 30 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| 1,3-Dichlorobenzene | 30 | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| 1,4-Dichlorobenzene | 4400 (224) | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| 1,4-Dichlorobenzene | 4400 (224) | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| 2,4-Dimethylphenol | | 16000 | <10 µg/kg | <100 | <10 | <10 | <10 |
| 2,4-Dinitrotoluene | | 3700 | <10 µg/kg | <100 | <10 | <10 | <10 |
| 2,6-Dinitrotoluene | | 1900 | <10 µg/kg | <100 | <10 | <10 | <10 |
| 2-Chloronaphthalene | | 390 | <10 µg/kg | <100 | <10 | <10 | <10 |
| 2-Chlorophenol | 3500 | - | <10 µg/kg | <100 | <3 | <3 | <3 |
| Acenaphthene | 84000 (57) | - | <10 µg/kg | 382 | <10 | <10 | <10 |
| Acenaphthylene | 83000 (86.1) | - | <10 µg/kg | 283 | <10 | 72 | <10 |
| Anthracene | 520000 | - | <10 µg/kg | 674 | <10 | 97 | <10 |
| Benzene | 27 | - | <5 µg/kg | <5 | <5 | <5 | <5 |
| Benzo(a)anthracene | 170 | - | <10 µg/kg | 1238 | <10 | 334 | <10 |

| Determinand | S4ULs (mg/kg) | EIC/AGS/CL:AIRE (mg/kg) | Laboratory Limit of Detection | PP_BH2 | PP_BH2 | PP_BH3 | PP_BH3 |
|---|---------------|-------------------------|-------------------------------|--------|--------|--------|--------|
| Benzo(a)pyrene | 35 | - | <10 µg/kg | 837 | <10 | 514 | 27 |
| Benzo(bk)fluoranthene | 44 | - | <10 µg/kg | 1483 | 16 | 940 | 33 |
| Benzo(ghi)perylene | 3900 | - | <10 µg/kg | 765 | <10 | 348 | <10 |
| Bis(2-ethylhexyl) phthalate | 85000 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Bromodichloromethane | | 2.1 | <4 µg/kg | <4 | <4 | <4 | <4 |
| Bromoform | 760 | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| Butylbenzyl phthalate | 940000 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Carbon tetrachloride (Tetrachloromethane) | 2.9 | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| Chlorobenzene | 56 | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| Chloroethane | | 960 | <6 µg/kg | <6 | <6 | <6 | <6 |
| Chloroform (trichloromethane) | 99 | -- | <5 µg/kg | <5 | <5 | <5 | <5 |
| Chloromethane | | 1 | <3 µg/kg | <3 | <3 | <3 | <3 |
| Chrysene | 350 | - | <10 µg/kg | 880 | <10 | 403 | <10 |
| cis-1-2-Dichloroethene | | 24 | <7 µg/kg | <7 | <7 | <7 | <7 |
| Dichloromethane (DCM) | | 270 | <7 µg/kg | <7 | <7 | <7 | <7 |
| Diethyl phthalate | 1500000 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Di-n-butyl phthalate | 15000 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Di-n-Octyl phthalate | 89000 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Ethylbenzene | 5700 (518) | - | <3 µg/kg | <3 | <3 | <3 | <3 |
| Ethylbenzene | 5700 (518) | - | <3 µg/kg | <3 | <3 | <3 | <3 |

| Determinand | S4ULs (mg/kg) | EIC/AGS/CL:AIRE (mg/kg) | Laboratory Limit of Detection | PP_BH2 | PP_BH2 | PP_BH3 | PP_BH3 |
|-----------------------------|---------------|-------------------------|-------------------------------|--------|--------|--------|--------|
| Fluoranthene | 23000 | - | <10 µg/kg | 644 | <10 | 629 | <10 |
| Fluorene | 63000 (30.9) | - | <10 µg/kg | 451 | <10 | <10 | <10 |
| Hexachlorobenzene | 110(0.2) | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Hexachlorobutadiene | 31 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Hexachlorobutadiene | 31 | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| Hexachloroethane | | 22 | <10 µg/kg | <100 | <10 | <10 | <10 |
| Indeno(123cd) pyrene | 500 | - | <10 µg/kg | 647 | <10 | 262 | <10 |
| Isopropylbenzene | | 12 | <3 µg/kg | <3 | <3 | <3 | <3 |
| Methyl Tertiary Butyl Ether | 7900 | - | <6 µg/kg | <6 | <6 | <6 | <6 |
| Methyl Tertiary Butyl Ether | 7900 | - | <6 µg/kg | <6 | <6 | <6 | <6 |
| Naphthalene | 190 (76.4) | - | <10 µg/kg | 216 | <10 | 54 | <10 |
| Naphthalene | 190 (76.4) | - | <27 µg/kg | <27 | <27 | <27 | <27 |
| o-Xylene | 6600 (478) | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| o-Xylene | 6600 (478) | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| p/m-Xylene | 6200 (625) | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| p/m-Xylene | 5900 (576) | - | <4 µg/kg | <4 | <4 | <4 | <4 |
| Pentachlorophenol | 400 | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Phenanthrene | 22000 | - | <10 µg/kg | 796 | 17 | 204 | 17 |
| Phenol | 440 (26000) | - | <10 µg/kg | <100 | <10 | <10 | <10 |
| Propylbenzene | | 40 | <4 µg/kg | <4 | <4 | <4 | <4 |

| Determinand | S4ULs (mg/kg) | EIC/AGS/CL:AIRE (mg/kg) | Laboratory Limit of Detection | PP_BH2 | PP_BH2 | PP_BH3 | PP_BH3 |
|--------------------------|---------------|-------------------------|-------------------------------|--------|--------|--------|--------|
| Pyrene | 54000 | - | <10 µg/kg | 675 | <10 | 580 | <10 |
| Styrene | | 35 | <3 µg/kg | <3 | <3 | <3 | <3 |
| Tetrachloroethene (PCE) | 19 | - | <3 µg/kg | <3 | <3 | <3 | <3 |
| Toluene | 56000 (869) | - | <3 µg/kg | <3 | <3 | <3 | <3 |
| Toluene | 56000 (869) | - | <3 µg/kg | <3 | <3 | <3 | <3 |
| trans-1-2-Dichloroethene | | 22 | <3 µg/kg | <3 | <3 | <3 | <3 |
| Trichloroethene (TCE) | 1.2 | - | <5 µg/kg | <5 | <5 | <5 | <5 |
| Vinyl chloride | 0.059 | - | <2 µg/kg | <2 | <2 | <2 | <2 |

-
- 10.2.9 As shown in Table 10.1 above, no concentration has exceeded the screening criteria (where available) for a commercial end use of the CLS installation. The concentrations of RHSs within the ground is considered low.
- 10.2.10 The following TPH compounds have been detected above the laboratory limit of detection
- >C21-C35 (Aliphatics) – 454 mg/kg in borehole PP_BH3
 - >EC21-EC35 (Aromatics) - 157 mg/kg in borehole PP_BH2 and 151 mg/kg in borehole PP_BH3
- 10.2.11 The TPH concentrations are found in the heavier, less mobile hydrocarbon ranges and is expected given the site's operational history.
- 10.2.12 The followings PAHs (SVOCs) were detected above the laboratory limit of detection:
- Acenaphthene - 382 µg/kg in borehole PP_BH2
 - Acenaphthylene - 283 µg/kg in borehole PP_BH2 and 72 µg/kg in borehole PP_BH3
 - Anthracene - 674 µg/kg in borehole PP_BH2 and 97 µg/kg in borehole PP_BH3
 - Benzo(a)anthracene - 1238 µg/kg in borehole PP_BH2 and 334 µg/kg in borehole PP_BH3
 - Benzo(a)pyrene - 837 µg/kg in borehole PP_BH2 and 514 µg/kg in borehole PP_BH3
 - Benzo(bk)fluoranthene - 1483 µg/kg in borehole PP_BH2 and 940 µg/kg in borehole PP_BH3
 - Benzo(ghi)perylene - 765 µg/kg in borehole PP_BH2 and 348 µg/kg in borehole PP_BH3
 - Chrysene - 880 µg/kg in borehole PP_BH2 and 403 µg/kg in borehole PP_BH3
 - Fluoranthene - 644 µg/kg in borehole PP_BH2 and 629 µg/kg in borehole PP_BH3
 - Fluorene - 451 µg/kg in borehole PP_BH2
 - Indeno(123cd) pyrene - 647 µg/kg in borehole PP_BH2 and 262 µg/kg in borehole PP_BH3
 - Naphthalene - 216 µg/kg in borehole PP_BH2 and 54 µg/kg in borehole PP_BH3
 - Phenanthrene - 796 µg/kg in borehole PP_BH2 and 204 µg/kg in borehole PP_BH3
 - Pyrene - 675 µg/kg in borehole PP_BH2 and 580 µg/kg in borehole PP_BH3
- 10.2.13 The reported concentrations are considered to be typical of general made ground in an industrial setting and likely to be associated with historic land uses.
- 10.2.14 In addition to the above, a number of analytes were reported in soil at concentrations exceeding the laboratory detection limit, including:
- Sodium;
 - Chloride;
 - Sulphate;
 - Carbazole;
 - Methyl alcohol; and
 - Acetone

10.3 Baseline Groundwater Quality

- 10.3.1 Groundwater monitoring and sampling was carried out at well PP_BH2 on 15th May 2014 and tested for compounds of potential concern.
- 10.3.2 A number of inorganic analytes were reported in groundwater at concentrations exceeding the laboratory at concentrations exceeding the laboratory detection limit, including:

-
- Sodium (265.9 mg/litre);
 - Chloride (435.5mg/litre);
 - Sulphate (124.1 mg/litre); and
 - Ammoniacal nitrogen (2.22 mg/litre).
- 10.3.3 The reported sodium, chloride and sulphate concentrations are considered to be consistent with their natural occurrence in the shallow groundwater in proximity to the tidal River Stour.
- 10.3.4 The presence of ammoniacal nitrogen in groundwater in this area is considered to be due to historic regional impacts.
- 10.3.5 A groundwater pH of 7.63, indicating approximately neutral groundwater conditions, was reported in the laboratory sample.
- 10.3.6 Organic compounds, including TPH, VOCs, SVOCs, alcohols/acetates and glycols were not reported at concentrations above the laboratory detection limit in the PP_BH2 groundwater sample.

10.4 Baseline Gas Assessment

- 10.4.1 No data were available at the time of the writing of this report.

10.5 Ground Conditions

- 10.5.1 The ground conditions beneath the Site comprised:
- made ground to a maximum depth of 2.9m bgl; overlying
 - sandy/silty/clayey Tidal Flat Deposits (Unproductive Strata) to a maximum depth of >5m bgl; overlying;
 - sandy gravel Storm Beach Gravels (Secondary-A aquifer) proven to a maximum depth of >5m bgl.
- 10.5.2 Water strikes were encountered within the Tidal Flat Deposits at depths ranging between 2.9m and 4.0m bgl. During the groundwater monitoring, resting water levels were recorded as 1.69m and 1.93m below the top of the well casing at PP_BH1 and PP_BH2 respectively.
- 10.5.3 Groundwater contours could not be constructed from two monitoring wells, however the groundwater elevation at PP_BH2 was observed to be lower than at PP_BH1, consistent with an easterly component of groundwater flow.

10.6 Field Observations of Contamination

- 10.6.1 Black colouration, potentially staining, was observed in the made ground between 2.4m and 2.9m bgl at location PP_BH2. However, no olfactory observations of impact were made from the same soils and the PID screening for the soils returned a value below the instrument detection limit (0.1ppm).
- 10.6.2 Suspected asbestos cement fragments were observed at a depth of 1.1m bgl during hand excavation at PP_BH3A. Excavation at this location was terminated at this depth in accordance with health and safety protocols, and the borehole was moved to the final PP_BH3 location.

11 OPERATIONAL PHASE SITE CONDITION REPORT

11.1 Operational Phase

11.1.1 This SCR, prepared in accordance with the EA “H5 Site Condition Report” guidance (*insert guidance ref*), contains information on the condition of the site during the operational phase of the facility. This shall be updated throughout the operational life of the site as required.

11.2 Site Condition Report Summary

| 4.0 Changes to the activity | |
|---|---|
| Have there been any changes to the activity boundary? If yes, provide a plan showing the changes to the activity boundary. | If yes, provide a plan showing the changes to the activity boundary. |
| Have there been any changes to the permitted activities? If yes, provide a description of the changes to the permitted activities | If yes, provide a description of the changes to the permitted activities |
| Have any ‘dangerous substances’ not identified in the Application Site Condition Report been used or produced as a result of the permitted activities? If yes, list them | If yes, list them |
| Checklist of supporting information | <ul style="list-style-type: none">• Plan showing any changes to the boundary (where relevant)• Description of the changes to the permitted activities (where relevant)• List of ‘dangerous substances’ used/produced by the permitted activities that were not identified in the Application Site Condition Report (where relevant) |

| 5.0 Measures taken to protect land | |
|---|---|
| Use records that you collected during the life of the permit to summarise whether pollution prevention measures worked. If you can’t, you need to collect land and/or groundwater data to assess whether the land has deteriorated. | |
| Checklist of supporting information | <ul style="list-style-type: none">• Inspection records and summary of findings of inspections for all pollution prevention measures• Records of maintenance, repair and replacement of pollution prevention measures |

| 6.0 Pollution incidents that may have had an impact on land, and their remediation | |
|---|--|
| Summarise any pollution incidents that may have damaged the land. Describe how you investigated and remedied each one. If you can’t, you need to collect land and /or groundwater reference data to assess whether the land has deteriorated while you’ve been there. | |
| Checklist of supporting information | <ul style="list-style-type: none">• Records of pollution incidents that may have impacted on land• Records of their investigation and remediation |

| 7.0 Soil gas and water quality monitoring (where undertaken) | |
|---|--|
| Provide details of any soil gas and/or water monitoring you did. Include a summary of the findings. Say whether it shows that the land deteriorated as a result of the permitted activities. If it did, outline how you investigated and remedied this. | |
| Checklist of supporting information | <ul style="list-style-type: none">• Description of soil gas and/or water monitoring undertaken• Monitoring results (including graphs) |

12 SURRENDER SITE CONDITION REPORT

- 12.1.1 At permit surrender, the following sections of the SCR template (EPR H5) will be completed and submitted to the EA as part of the permit surrender application. Information that has been gathered over the lifetime of the Permit will be used to identify whether the land is in a satisfactory condition. If necessary, surrender reference data will be collected and remediation will be undertaken if required.

8.0 Decommissioning and removal of pollution risk

Describe how the site was decommissioned. Demonstrate that all sources of pollution risk have been removed. Describe whether the decommissioning had any impact on the land. Outline how you investigated and remedied this.

| | |
|--|--|
| Checklist of supporting information | <ul style="list-style-type: none">• Site closure plan• List of potential sources of pollution risk• Investigation and remediation reports (where relevant) |
|--|--|

9.0 Reference data and remediation (where relevant)

Say whether you had to collect land and/or groundwater data. Or say that you didn't need to because the information from sections 3, 4, 5 and 6 of the Surrender Site Condition Report shows that the land has not deteriorated.

If you did collect land and/or groundwater reference data, summarise what this entailed, and what your data found. Say whether the data shows that the condition of the land has deteriorated, or whether the land at the site is in a "satisfactory state". If it isn't, summarise what you did to remedy this. Confirm that the land is now in a "satisfactory state" at surrender.

| | |
|--|--|
| Checklist of supporting information | <ul style="list-style-type: none">• Land and/or groundwater data collected at application (if collected)• Land and/or groundwater data collected at surrender (where needed)• Assessment of satisfactory state• Remediation and verification reports (where undertaken) |
|--|--|

10.0 Statement of site condition

Using the information from sections 3 to 7, give a statement about the condition of the land at the site. This should confirm that:

- the permitted activities have stopped
 - decommissioning is complete, and the pollution risk has been removed
 - the land is in a satisfactory condition
-

13 CONCLUSIONS

- 13.1.1 A desk-based review has been undertaken that conforms to the requirements of a Baseline Report that includes the following:
- Stage 1 - Identify hazardous substances used, produced or released at the proposed installation;
 - Stage 2 - Identify relevant hazardous substances used, produced or released at the installation from the list of hazardous substances identified in Stage 1;
 - Stage 3 – Undertake an assessment of site-specific pollution possibility for relevant hazardous substances;
 - Stage 4 – Evaluation of site history and potential for relevant hazardous substances to be present in soils and groundwater;
 - Stage 5 – Evaluation of environmental setting to determine the fate of potential emissions of relevant hazardous substances;
 - Stage 6 – Site characterisation that synthesises findings of Stage 5 and 6 on the basis of a Conceptual Site Model;
 - Stage 7 – Need for further site investigation;
 - Stage 8 – Production of baseline report.
- 13.1.2 The Relevant Hazardous Substances identified for the CLS facility have been shown to include the following:
- Diethyl ether;
 - Diethyl ketone;
 - Diisopropyl ether;
 - Dioxane;
 - Methylene chloride;
 - m-Xylene;
 - n-Heptane;
 - n-Hexane;
 - Tert-butyl methyl ether;
 - Tetrahydrofuran;
 - Toluene; and
 - Waste Solvents
- 13.1.1 The risk to soil, groundwater and surface water has been minimised through a variety of measures and controls delivered through design and operational protocols for the CLS facility. These include:
- No underground storage tanks are in place or proposed for the facility;
 - The raw materials and products are stored within a bunded building which have bunded storage areas as shown in figures 5.1 to 5.6 above. The building has sealed internal drainage and impermeable floors.
 - All external solvent stores are situated on impermeable made ground to prevent fugitive emissions to ground should spills/ leaks occur. These areas are surrounded by kerbing which is itself situated lower than the surrounding gravelled areas.

- All chemicals will be subject to appropriate storage and handling practices which are described and enforced through the CLS EMS and SOPs.
 - The site has a spillage procedure to ensure that any risk from spillages is minimised and are cleaned up as soon as a spill is detected. Emergency spill kits will be available across the site
 - Accidental spills in external areas could potentially enter the surface water drainage system shown in the drainage plans in Appendix A of this report. The effects of accidental spills are mitigated by surface water systems draining to the Discovery Park WWTP where they can be isolated.
 - All drains are capped. It is the operator's intention to install tanks in the future. The foul drainage system is pumped and can be electrically isolated if required
 - The receptors considered in the site-specific pollution potential included: made ground, Tidal Flat Deposits (Unproductive Strata), the underlying Storm Beach Gravels (Secondary-A aquifer) and groundwater. Water strikes were encountered within the Tidal Flat Deposits at depths ranging between 2.9m and 4.0m bgl.
- 13.1.3 The assessment of site-specific pollution potential concluded that RHSs used, produced or emitted on the CLS facility represent a low risk to soil and groundwater receptors on the site.
- 13.1.4 On the basis of this assessment the baseline quality of the soil and groundwater has been defined through a review of a historical report and intrusive investigation relevant to the CLS facility. Generally low organic and inorganic contamination have been identified in the ground underlying the site with a few TPHs and SVOCs exceedances of the adopted screening criteria recorded across the CLS facility.
- 13.1.5 Inorganic contaminants identified in the groundwater demonstrated generally low concentrations with the exception of exceedances recorded for sodium, chloride and sulphate in PP_BH2.
- 13.1.6 A review of the contaminants of concern associated with the RHSs identified on the site concluded that the baseline quality has been characterised for the majority of contaminants of concern associated with RHS.
- 13.1.1 The chemicals listed below are not included in the URS investigation analysis suite therefore a baseline concentration cannot be provided:
- Diethyl ether;
 - Diethyl ketone;
 - Diisopropyl ether;
 - Dioxane;
 - n-Heptane;
 - n-hexane; and
 - Tert-butyl methyl ether
- 13.1.7 For any contaminants not characterised, it has been also concluded that these substances are not expected to be present on the site as result of historical land-use on or near the CLS facility.
- 13.1.8 In accordance with the conclusions of historical reporting, the baseline dataset presented herein provided no evidence for a significant impact on groundwater quality by leachate generated from the made ground. It is concluded that there is sufficient existing data on the RHS to baseline the site and therefore that further ground investigation is not required. The baseline will be reviewed following full characterisation of waste/residues once the facility is commissioned and operational.

GLOSSARY

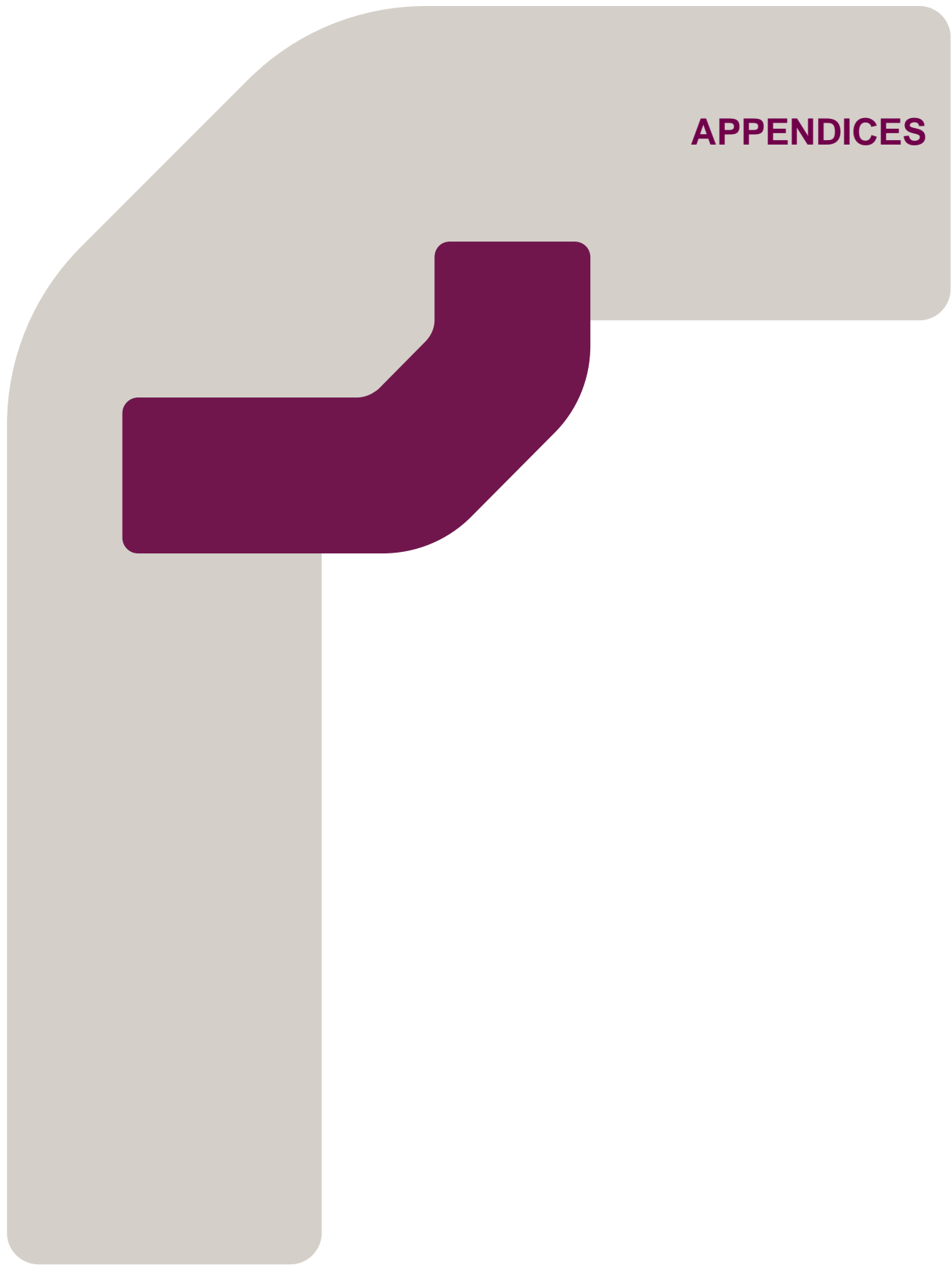
| | |
|--------------------|---|
| • ACN | Acetonitrile (Methyl cyanide) |
| • AOD | Above ordnance datum |
| • API | Active pharmaceutical ingredient |
| • ASC | Application site condition |
| • ASCR | application site condition report |
| • bgl | Below ground |
| • CDI | Carbonyldiimidazole |
| • CC | Chemically contaminated |
| • CHIP regulations | Chemicals (Hazard Information and Packaging for Supply) |
| • CLP | Classification, Labelling and Packaging |
| • CLS | Concept Life Sciences |
| • CSM | Conceptual Site Model |
| • DAA | Directly associated activities |
| • DMSO | Dimethyl sulphoxide |
| • EA | Environment Agency |
| • EMS | Environmental Management Systems |
| • ERA | Environmental Risk Assessment |
| • ECHA | European Chemicals Agency |
| • FC | Fume cupboard |
| • H/C | |
| • HEPA | High-efficiency particulate air. |
| • HDPE | high-density polyethylene |
| • IED | Industrial Emissions Directive |
| • LDL | Laboratory detection limit |
| • L | Litres |
| • MSDS | Material safety data sheet |
| • MTBE | Methyl tert-butyl ether |
| • PAH | Polycyclic aromatic hydrocarbon |
| • PC | Potentially contaminated |
| • RHS | Relevant Hazardous Substances |
| • R&D | Research and development |
| • RSM | Regulated starting material |
| • SVOC | Semi-volatile organic compounds |
| • SCR | Site condition report |

-
- SOP Standard operating procedures
 - TABCl Tetrabutylammonium chloride
 - TIC Tentatively identified compound
 - THF Tetrahydrofuran
 - UN United Nations
 - VOC Volatile organic compound
 - WWTP Wastewater treatment plant

REFERENCES

1. H5 Site Condition Report guidance - <https://www.gov.uk/government/publications/environmental-permitting-h5-site-condition-report>
2. European Commission Guidance - [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52014XC0506\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52014XC0506(01)&from=EN)
3. European Chemicals Agency (ECHA) database - <https://echa.europa.eu>
4. European Commission Guidance concerning baseline reports - [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0506\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0506(01)&from=EN)
5. Magic Map - <https://magic.defra.gov.uk/MagicMap.aspx>
6. British Geological Survey, Geology of Britain Viewer - <http://mapapps.bgs.ac.uk/geologyofbritain/home.html>
7. Environment Agency public register - https://environment.data.gov.uk/public-register/api/search?_postcode=CT13+9ND&dist=1&eastings=633428&northing=159463
8. Suitable 4 Use Levels (S4ULs) - <https://www.lqm.co.uk/publications/s4ul/>
9. Environment Agency SR2 Report - <https://www.gov.uk/government/publications/human-health-toxicological-assessment-of-contaminants-in-soil>
10. Category 4 Screening Levels (C4SLs), developed by CL:AIRE - <https://www.clare.co.uk/projects-and-initiatives/category-4-screening-levels>
11. Generic Assessment Criteria (GAC) developed by CL:AIRE - <https://www.clare.co.uk/component/phocadownload/category/8-initiatives?download=44:gac-report-6-12-09b>

APPENDICES



Appendix A

Site Plans

Appendix B

URS Baseline Soil and Groundwater Investigation, June 2014

Appendix C

Landmark Envirocheck Report

Appendix D

Safety Data Sheets

Appendix E

Pfizer Building 901 Decommissioning Report

Appendix F

Environment Agency Nature and Heritage Conservation Screening Report