IP 0002/05/D

MEDICHEM MANUFACTURING (MALTA) LTD, HAL FAR

LAND AND GROUNDWATER RISK ASSESSMENT

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Quality Assurance

Medichem Manufacturing (Malta) Ltd, Hal Far
Land and Groundwater Risk Assessment
January 2017

Report for: Medichem Manufacturing (Malta) Ltd, Hal Far

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Rev	Date	Details	Prepared by	Reviewed by	Approved by
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LAND AND GROUNDWATER RISK ASSESSMENT

Introduction

1. En-Sure Ltd was commissioned by Medichem Manufacturing (Malta) Ltd to carry out a land and groundwater risk assessment for its pharmaceutical facility at Hal Far, as requested by the Environment and Resources Authority (ERA) as part of the Integrated Pollution Prevention and Control (IPPC) permit for the facility.

2. The facility, hereinafter referred to as the "Scheme", comprises a factory for the manufacture of Active Pharmaceutical Ingredients. The site is located at HF-61, Hal Far Industrial Estate (**Figure 1**).

3. The Scheme is operated by Medichem Manufacturing (Malta) Ltd, and is regulated by IPPC permit number IP 0002/05/D; the Scheme also has an Environmental Management System certified to the ISO 14001:2004 standard. Medichem Manufacturing (Malta) Ltd is hereinafter referred to as 'the Operator'.

Terms of Reference

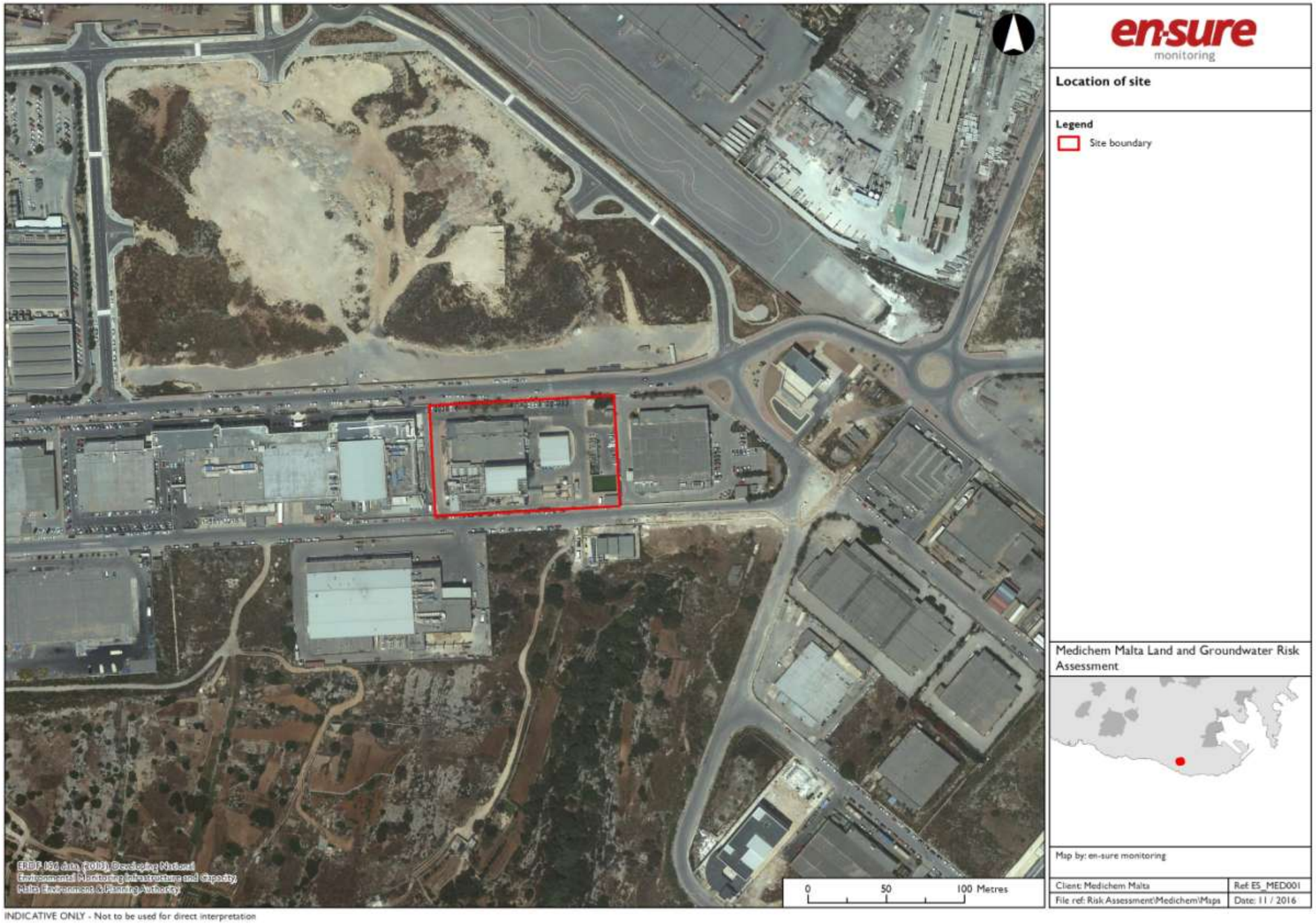
4. Table 1.4.1 (Reference 6) of the IPPC permit requires the:

> *Submission of a land and groundwater risk assessment and, if required, a monitoring strategy and baseline report in line with European Commission and MEPA[1] guidance pursuant to Regulations 9(3) and 16(2) of the Industrial Emissions (IPPC) Regulations.*

5. According to the above guidance from the European Commission on preparing baseline reports, the first step is to determine whether a baseline report is required. Baseline land / groundwater measurements are only required when the activity involves the use, production, or release of relevant hazardous substances and taking into account the possibility of soil and groundwater contamination by the Scheme. This report therefore presents a risk assessment to determine whether baseline monitoring is required.

[1] In May 2016, the former MEPA (the Malta Environment & Planning Authority) was split into two separate entities: the Planning Authority (PA) and the Environment and Resources Authority (ERA).

Figure 1: Site location



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Description of the Site and the Surroundings

Location

6. The Scheme site covers an area of approximately 8,437 m^2 and is located in the Hal Far Industrial Estate, as shown in **Figure 1**. Access is through a surfaced road.

History

7. The history of the Scheme site and its surroundings has been obtained through a review of available documentation.

8. The 1915 survey sheet for the area shows the Scheme site and its surroundings as predominantly unused garigue and agricultural land.

9. One of the two runways of the former Hal Far airfield, which operated between the 1920s and the 1970s, was located immediately north of the Scheme site, as shown in **Figure 2** and **Figure 3** (the approximate location of the site is outlined in red). The airfield was heavily bombed during World War II.

10. The IPPC application submitted for the Scheme in 2004, as well as aerial photos from 1998 (**Figure 4**) and 2004 indicate that around half the Scheme site was a factory that had been constructed by the former Malta Development Corporation (now Malta Industrial Parks Ltd) in 1979 as part of the establishment of the first twelve factories at the Hal Far Industrial Estate. This building was originally used by Polycane Ltd, which used to manufacture plastic furniture such as sunbeds, chairs, tables, and other garden furniture, and was vacant before Medichem took over the site. The other half of the Scheme site adjacent to this factory was unbuilt at the time.

11. The Scheme started operation in 2005, with a high-potency active pharmaceutical ingredient (HPAPI) research unit being commissioned in 2014.

Figure 2: 1953 map of Hal Far airfield[2]

[2] *RAF Hal Far (HMS Falcon)* www.ronaldv.nl/abandoned/airfields/MT/malta.html#halfar. The approximate location of the Scheme site is marked in red.

Figure 3: 1960 aerial photo[3]

[3] *RAF Hal Far (HMS Falcon)* www.ronaldv.nl/abandoned/airfields/MT/malta.html#halfar. The approximate location of the Scheme site is marked in red.

Figure 4: 1998 aerial photo

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Surrounding Land Uses

12. The land uses covering an area of approximately 250 m around the Scheme site are shown in **Figure 6**.

13. The predominant land uses in the surrounding area are industrial (**Figure 5**), predominantly manufacturing (including other pharmaceutical facilities) and goods / freight terminals.

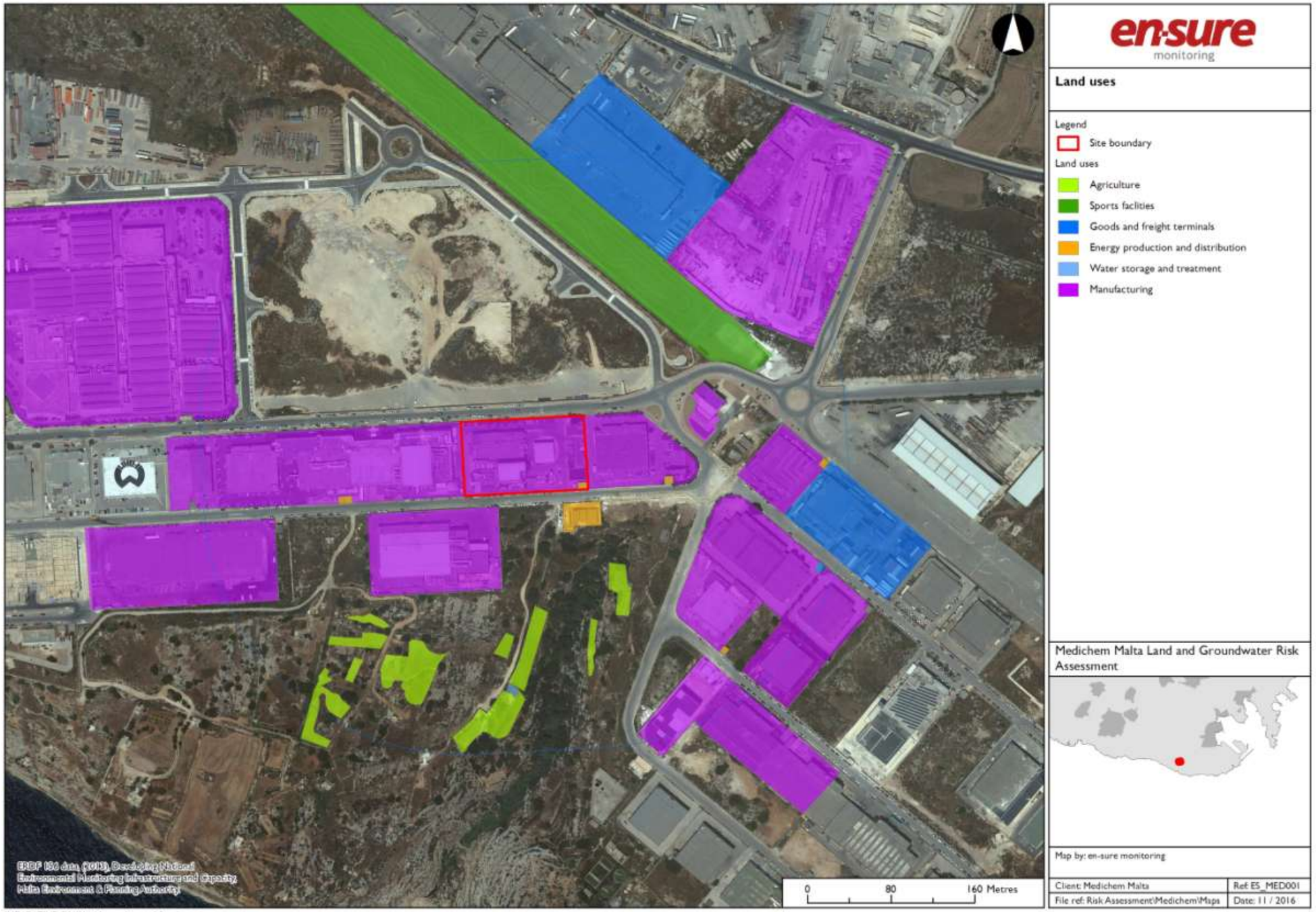
Figure 5: Industrial uses

14. There are a number of electricity substations servicing the area, and a transformer plant operated by Enemalta. A drag racing facility makes use of one of the former runways found north of the Scheme site.

15. Some cultivated agricultural land is found along both sides of the Wied Żnuber valley (which is located south of the Scheme site).

16. There are no residential properties within 250 m of the Scheme site.

Figure 6: Land uses



Scheme Description

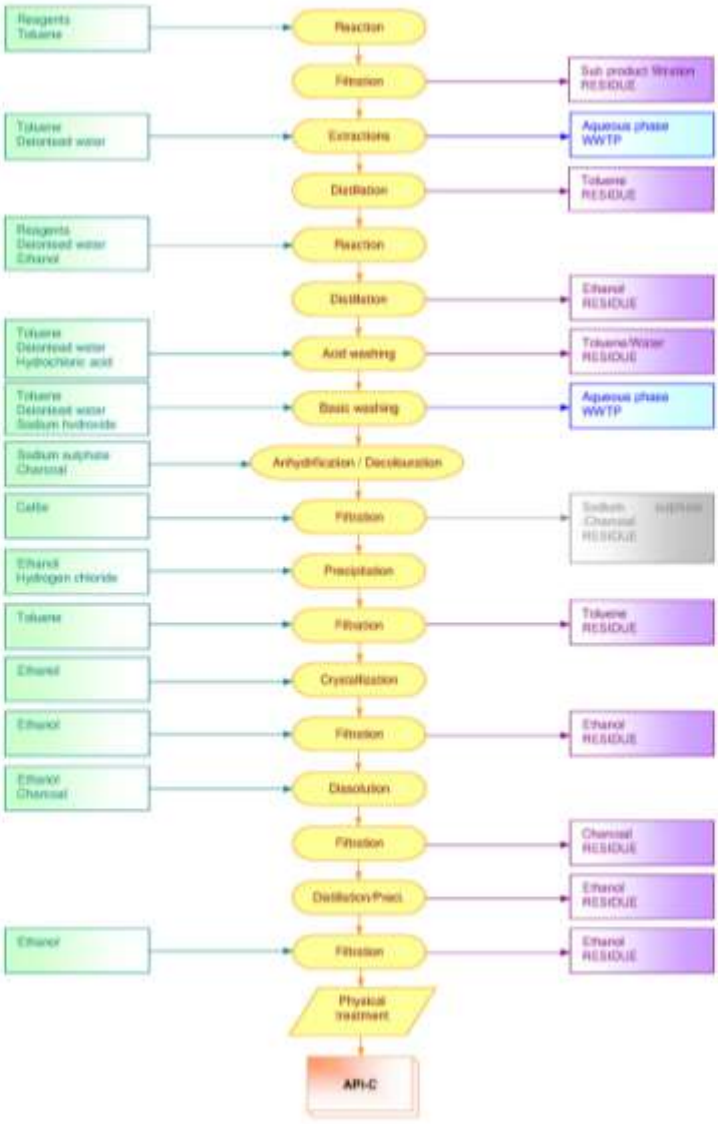
17. A meeting and site visit were held with Ing. Mark Debono, EPHS Manager for the facility, on 18th November 2016. Relevant documentation, including key sections of the IPPC permit and a sample of the records held on site, were also reviewed.

Production Activities

18. The Scheme carries out the synthesis of potent and non-potent active pharmaceutical ingredients (APIs).

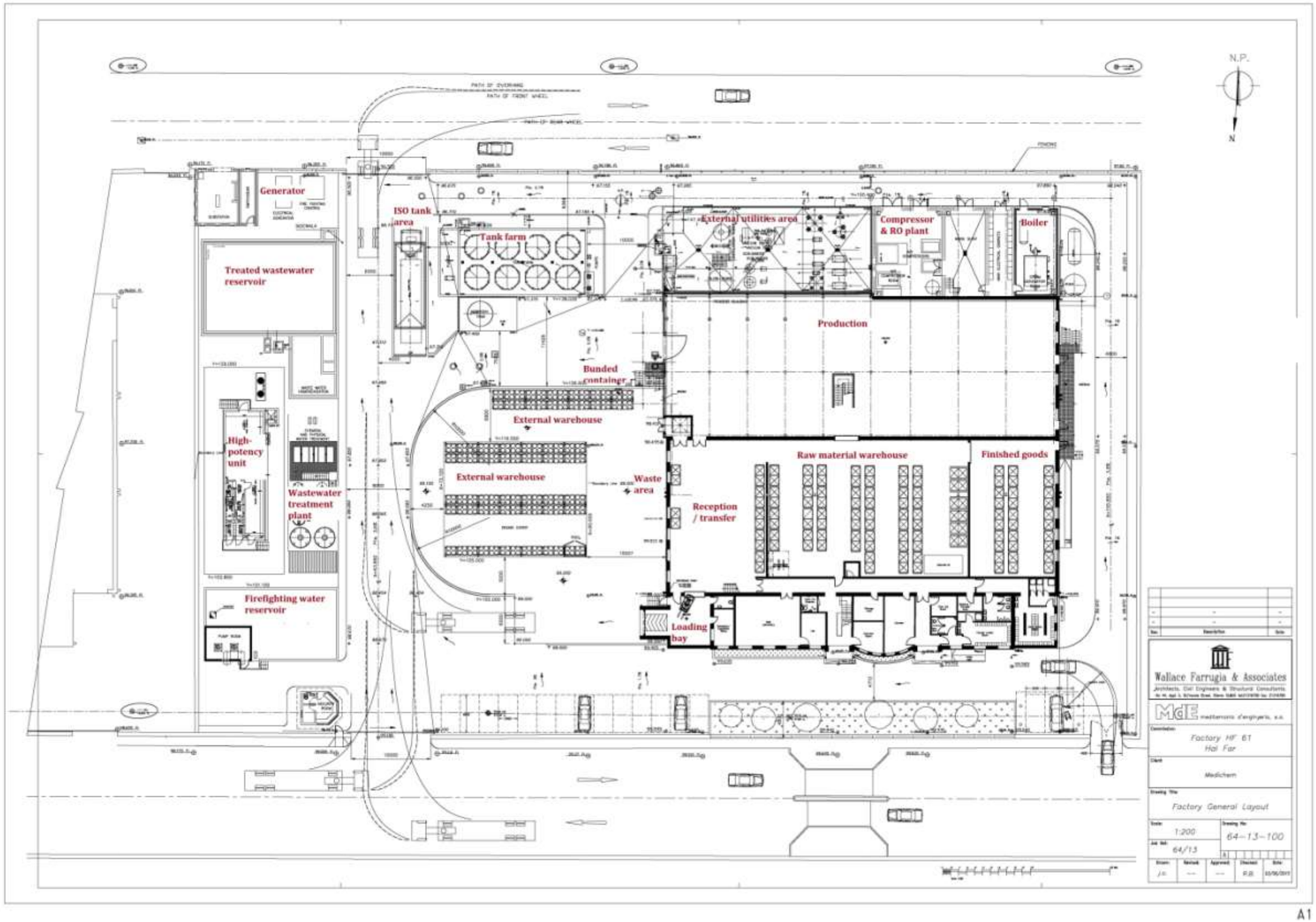
19. An example of the API production process is shown in **Figure 7**.

Figure 7: Example API production flow diagram



20. The layout of the Scheme at ground floor level is shown in **Figure 8**.

Figure 8: Scheme layout (ground floor)



Identification of Hazardous Substances, Waste and Emissions

Raw Materials and Products

21. The Scheme produces a range of API products, varying from time to time depending on market demands and the developing technical expertise of the company. The products manufactured are commercially confidential; however, they include non-potent and high-potency drugs and the annual quantity manufactured was 6 tonnes in 2015, and 11 tonnes in 2014.

22. Information on the raw materials used in the manufacture of APIs is included in **Table 1**. This information is grouped by type, since the Scheme considers the raw data to be commercially confidential.

Table 1: Raw materials (API production)

Type	Risk phrases	Quantity used in 2015 (tonnes)
Starting materials	R22, R24, R25, R34, R36, R37, R38, R39, R41, R53	11.5
Solvents	R10, R11, R19, R20, R21, R22, R23, R24, R25, R36, R37, R38, R39, R40, R41, R48, R50, R53, R61, R63, R65, R66, R67	178
Reagents	R10, R11, R12, R14, R15, R20, R21, R22, R23, R24, R25, R26, R29, R31, R34, R35, R36, R37, R38, R39, R40, R41, R43, R48, R50, R52, R53, R61, R63	16.3
Catalysts	R10, R11, R20, R22, R35	0.04

23. The Scheme also uses the raw materials shown in **Table 2** in the associated activities carried out on site.

Table 2: Raw materials (associated activities)

Substance	Use	Annual quantity used	Physical state	Hazard
LPG	Boiler	32,775 m^3	Gas (at RTP)	Hazardous (extremely flammable, may explode if heated, may cause genetic defects, may cause cancer)
Diesel	Generator	2 m^3	Liquid	Hazardous (Flammable, aspiration hazard, acute toxicity, skin corrosion / irritation, carcinogenic, specific target organ toxicity - repeated exposure, hazardous to the aquatic environment - long-term and acute hazards)
Nitrogen	Production	14,888 m^3	Gas (at RTP)	Hazardous (may cause cryogenic burns or injury, may displace oxygen and cause rapid suffocation)
Biocide	Cooling tower	24 L	Liquid	Hazardous (corrosive to skin, eyes, irritation of upper respiratory tract, target organ damage if ingested)
Continuum AT4505 (corrosion inhibitor)		175 L	Liquid	Hazardous (corrosive to skin, eyes, irritating to respiratory system)

Substance	Use	Annual quantity used	Physical state	Hazard
Sodium metabisulfite	RO plant	75 kg	Powder (soluble in water)	Hazardous (acute toxicity, serious eye damage)
Sodium hypochlorite		2 L	Liquid	Hazardous (skin corrosion)
Hypersperse (deposit control agent)		50 L	Liquid	Not hazardous
Vacuum pump oil	Vacuum pumps	3,600 L	Liquid	Hazardous (causes serious eye damage, toxic to aquatic life)
Coagulant	Wastewater treatment plant	200 L	Liquid	Hazardous (serious eye damage / eye irritation)
Flocculant		40 L	Emulsion	Not hazardous
50% NaOH		100 kg	Liquid	Hazardous (very hazardous in case of skin contact, eye contact, ingestion; toxic to lungs)
Conc. H_2SO_4		Minimal (none used in 2015)	Liquid	Hazardous (very hazardous in case of skin contact, eye contact, ingestion, inhalation; may be toxic to kidneys, lungs, heart, cardiovascular system, upper respiratory tract, eyes, teeth)

Waste

24. The hazardous waste generated by the Scheme and removed from site in 2015 is identified in **Table 3**. Only hazardous waste is considered in this assessment, since non-hazardous waste is not a significant land or groundwater contamination risk.

Table 3: Hazardous waste produced by Medichem

EWC code	Description (according to Decision 2014/955/EU)	Annual quantity (tonnes)
07 05 01*	Aqueous washing liquids and mother liquors	6.0
07 05 03*	Organic halogenated solvents, washing liquids and mother liquors	0.1
07 05 04*	Other organic solvents, washing liquids and mother liquors	1.7
07 07 01*	Aqueous washing liquids and mother liquors	1.0
07 07 03*	Organic halogenated solvents, washing liquids and mother liquors	1.3
07 07 04*	Other organic solvents, washing liquids and mother liquors	177.3
07 07 10*	Other filter cakes and spent absorbents	0.7
14 06 03*	Other solvents and solvent mixtures	52.4
15 01 10*	Packaging containing residues of or contaminated by hazardous substances	1.4
15 02 02*	Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by hazardous substances	0.5
16 03 05*	Organic wastes containing hazardous substances	0.6
18 01 08*	Cytotoxic and cytostatic medicines	2.1

25. The facility also used to accept wastes produced by an adjacent pharmaceutical plant, Combino Pharm, for temporary storage prior to export. The wastes

accepted in 2015 are listed in **Table 4**. Such waste used to be stored and exported in the same manner as Medichem's own waste; however, the practice of accepting Combino Pharm's waste has now been discontinued.

Table 4: Hazardous waste accepted from Combino Pharm in 2015

EWC code	Description (according to Decision 2014/955/EU)	Annual quantity (tonnes)
07 05 01*	Aqueous washing liquids and mother liquors	4.9
07 05 04*	Other organic solvents, washing liquids and mother liquors	1.7

Emissions to Air

26. Emissions points to air from the Scheme are identified in **Table 5** and **Figure 9**.

Table 5: Emissions to air

Ref.	Source
1	Production
2	Solvent / mother liquor tanks (waste / raw materials)
3	Gas-fired boiler
4a	HVAC plant exhaust
4b	HVAC exhaust from high-potency laboratory
5	Cooling towers

27. The Scheme also has an electricity generator for the provision of electricity in the case of a mains power failure; the generator runs on diesel and is used minimally.

28. The IPPC permit sets the following limit values for Volatile Organic Compounds (VOCs):

- 5% of the total solvent input; or
- 150 mgC/Nm^3 for emissions from the scrubber and a fugitive emission value of 5% of the solvent input.

29. The Scheme complies with these limit values, having an annual average concentration of VOCs from the scrubber of 0.7 mgC/m^3 (emission load estimated at 0.3 tonnes in 2015) and a fugitive emission value of 0.6% of the solvent input (1.4 tonnes in 2015).

30. Stricter limits are also set for certain VOCs:

- A limit value of 2 mg/Nm^3 applies to substances having the risk phrases R45, R46, R49, R60 or R61 (hazard statements H340, H350, H350i, H360D or H360F) when the total mass flow of the sum of such compounds is ≥10 g/h; and
- A limit value of 20 mg/Nm^3 applies to substances with the risk phrases R40 or R68 (hazard statements H341 or H351) when the total mass flow of such compounds is ≥100 g/h.

31. In 2015, the Scheme used one VOC having the risk phrase R61 and one VOC having the risk phrase R40. However, the total mass flow was 0.2 g/h and 73 g/h respectively; therefore the above limit values do not apply.

Wastewater Treatment

32. The Scheme also has a physico-chemical wastewater treatment plant which receives effluent from washing of floors as well as lightly-contaminated production effluent (e.g. wash water from reactors). The plant can also receive spills from the production area; these are collected in a separate reservoir and the nature of the spill verified before it is decided whether to collect and export the effluent as hazardous waste or to treat it in the wastewater treatment plant.

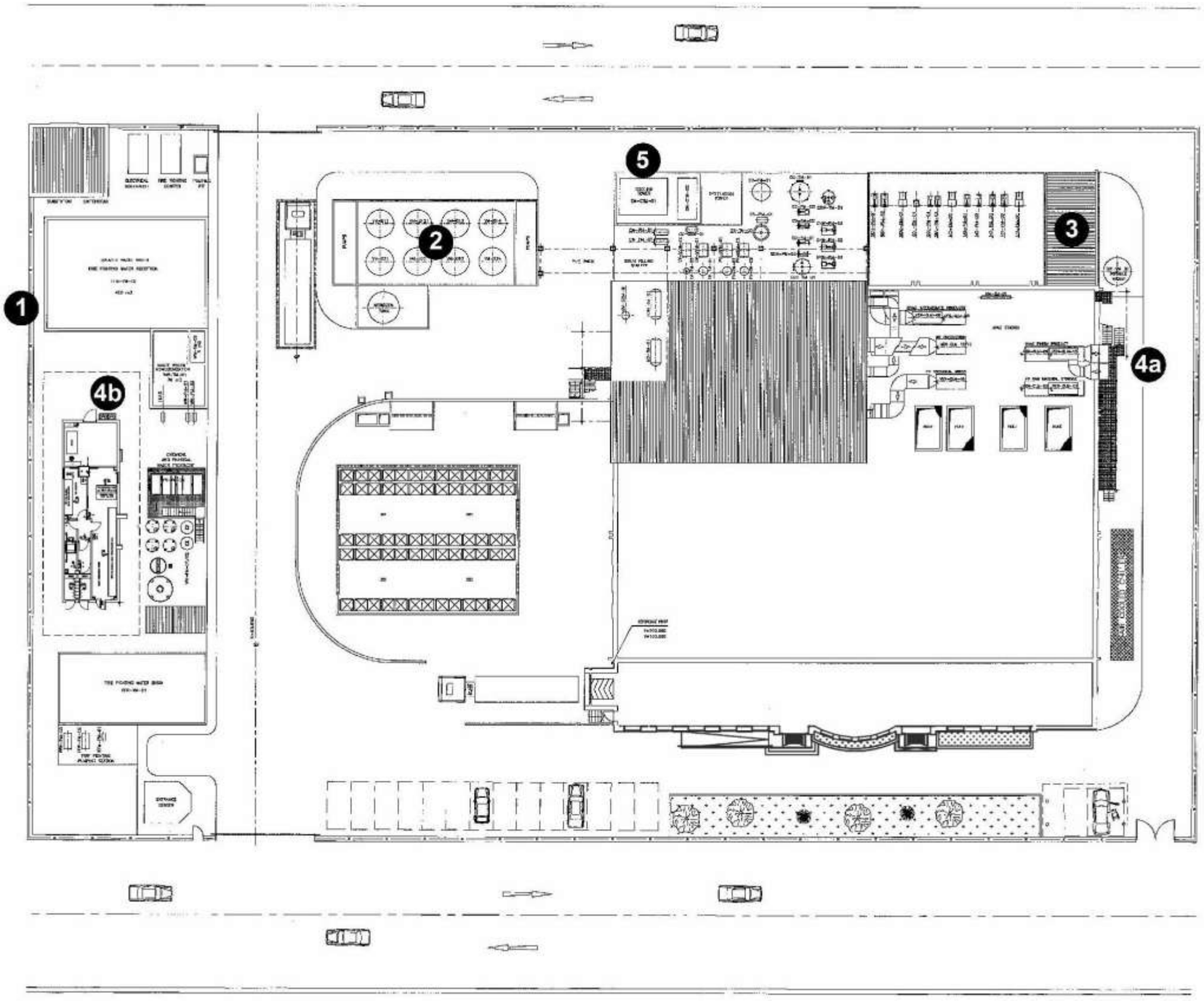
33. The wastewater treatment process consists of:

- pH adjustment;
- coagulation;
- flocculation; and
- sedimentation.

34. Treated effluent from the plant is tested for compliance with the Sewer Discharge Control Regulations (LN 139 of 2002 as amended, S.L. 545.08) before being discharged to the mains sewer. Solid residue from the press filter is disposed of to landfill as non-hazardous waste[4].

[4] The waste was tested by the Scheme and confirmed by WasteServ to be non-hazardous (email from Daniela Grech, 19th June 2009).

Figure 9: Emission points to air



35. **Table 6** identifies the potential pollution risk of the substances considered in the preceding section by considering whether they are hazardous, and also the properties relevant to whether the substance has the potential to pollute land / groundwater. Only the substances classified as relevant are considered further in this risk assessment.

Table 6: Potential pollution risk from substances, waste and emissions

Activity	Substances / waste / emissions	Relevance to land / groundwater contamination	Justification
Raw materials (API production)	Starting materials	Relevant	Hazardous, may be soluble even if solid
	Solvents	Relevant	Hazardous liquids
	Reagents	Relevant	Hazardous, may be soluble even if solid
	Catalysts	Not relevant	Insoluble solids, would not travel far if spilt
Raw materials (associated activities)	LPG	Not relevant	Gaseous, therefore has limited potential for land / groundwater contamination
	Diesel	Relevant	Hazardous liquid
	Nitrogen	Not relevant	Gaseous, therefore has limited potential for land / groundwater contamination
	Biocide	Relevant	Hazardous liquid
	Continuum AT4505	Relevant	Hazardous liquid
	Sodium metabisulfite	Relevant	Hazardous solid, soluble in water
	Sodium hypochlorite	Relevant	Hazardous liquid
	Hypersperse	Not relevant	Not hazardous
	Vacuum pump oil	Relevant	Hazardous liquid
	Coagulant	Relevant	Hazardous liquid
	Flocculant	Not relevant	Not hazardous
	50% NaOH	Relevant	Hazardous liquid
	Conc. H_2SO_4	Relevant	Hazardous liquid
Products	Non-potent and high-potency APIs	Relevant	Hazardous, soluble in water
Waste	Waste containing solvents	Relevant	Hazardous, mostly liquid
	Contaminated packaging & absorbents	Relevant	Hazardous contaminants may travel to land / groundwater
	Cytotoxic / cytostatic medicines	Relevant	Hazardous, soluble if solid
Emissions to air	Point 1: Emissions from production	Relevant	Hazardous VOCs and APIs may be released
	Point 2: VOCs from solvent / mother liquor tanks	Relevant	Hazardous VOCs may be released

Activity	Substances / waste / emissions	Relevance to land / groundwater contamination	Justification
	Point 3: Combustion by-products from boiler	Not relevant	Run on LPG, which is a very clean fuel; additionally, most emissions would be gaseous
	Point 4a: HVAC plant exhaust	Relevant	Hazardous APIs may be released
	Point 4b: High-potency lab HVAC exhaust	Relevant	Hazardous APIs may be released
	Point 5: Bacteria from cooling towers	Not relevant	There is no foreseeable pollutant linkage to land or groundwater
	Combustion by-products from emergency generator	Not relevant	Used very rarely, and most emissions would be gaseous
Wastewater management	Wastewater prior to treatment	Relevant	May be contaminated with solvents and APIs
	Wastewater after treatment	Not relevant	Tested and found to conform to the Sewer Discharge Control Regulations (LN 139 of 2002 as amended, S.L. 545.08)

Risk Assessment Methodology

Source-Pathway-Receptor Linkage

36. An environmental risk occurs when there is a means by which a hazard can result in a deleterious impact on the surrounding environment, i.e. receptors. The presence of a hazard alone does not constitute a risk. A risk is only present if there is a pathway which links the source (hazard) to the receptor. This is known as the source-pathway-receptor linkage.[5]

37. Environmental risk assessment is the process by which source-pathway-receptor linkages are identified and evaluated. If any of the three elements are absent then there is no complete linkage and thus no unacceptable risk.

Risk Assessment Criteria

38. If a source-pathway-receptor linkage is found, the magnitude of a risk is a function of the consequences of pollution and the likelihood that such pollution will occur.

[5] Defra (2002) *Groundwater Protection Code: Petrol Stations and other Fuel Dispensing Facilities involving Underground Storage Tanks* http://archive.defra.gov.uk/environment/quality/water/waterquality/ground/documents/groundwater-petrol.pdf.

39. The risk criteria being applied to this assessment are based on a matrix consistent with the Australian Standard AS4360 on Risk Management and ISO 31010: *Risk management: Risk assessment techniques*.

40. **Table 7** presents criteria for assessing environmental consequences, whereas **Table 8** presents criteria for assessing the likelihood of the event occurring.

41. The overall risk level is then determined by combining the two factors, using the matrix in **Table 9**.

Table 7: Criteria for assessing environmental consequences

Severity level	Effects on natural environment
1: Insignificant	Limited damage to minimal area of low significance.
2: Minor	Minor effects on biological or physical environment. Minor short/medium-term damage to small area of limited significance.
3: Moderate	Moderate effects on biological or physical environment (e.g. air, water) but not affecting ecosystem function. Moderate short/medium-term widespread impacts (e.g. significant spills).
4: Major	Serious environmental effects with some impairment of ecosystem function. Relatively widespread medium-long term impacts.
5: Catastrophic	Very serious environmental effects with impairment of ecosystem function. Long term, widespread effects on significant environment (e.g. national park).

Table 8: Measure of likelihood

Level	Descriptor	Description	Guideline frequency
A	Almost Certain	Consequence is expected to occur in most circumstances	Occurs more than once per month
B	Likely	Consequence will probably occur in most circumstances	Occurs once every 1 month - 1 year
C	Occasional	Consequence should occur at some time	Occurs once every 1 year - 10 years
D	Unlikely	Consequence could occur at some time	Occurs once every 10 years - 100 years
E	Rare	Consequence may only occur in exceptional circumstances	Occurs less than once every 100 years

Table 9: Risk matrix

Likelihood	Environmental consequence					No pollutant linkage
	1: Insignificant	2: Minor	3: Moderate	4: Major	5: Catastrophic	
A: Almost Certain	Low	Moderate	Extreme	Extreme	Extreme	None
B: Likely	Low	Moderate	High	Extreme	Extreme	
C: Occasional	Very low	Moderate	High	High	Extreme	
D: Unlikely	Very low	Low	Moderate	High	High	
E: Rare	Very low	Low	Moderate	Moderate	High	

Risk Assessment

Overview

42. As described, the Scheme's operations include manufacture, storage and handling of hazardous substances and waste, as well as the generation of emissions and discharges, which, without mitigation, could create a risk to land and groundwater through underground, surface, and airborne pollution.

43. **Table 10** summarises potential sources of pollution and their respective pathway to the relevant receptors. The generation of used firefighting water in the event of a fire has also been considered.

44. **Table 10** also includes the mitigation measures adopted to mitigate such risks. It is noted that all the mitigation measures in the Table are already implemented at the Scheme unless otherwise mentioned.

Table 10: Pollution pathway identification and mitigation measures

Source	Pathway	Receptor	Mitigation measures	Notes
Spillage of raw materials (starting materials, reagents) used in API production	Permeable strata above water table[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in the raw materials warehouse (**Figure 10**), which has a concrete floor covered by an impermeable resin. • Floor drains in the raw materials warehouse lead to the wastewater treatment plant. • Separate drains are present to collect spills; these lead to a dedicated 4 m^3 reservoir (labelled as *2: process drains reservoir* in **Figure 25**) where the spill can be retained and inspected / tested before a decision is made regarding whether the spill can be treated in the wastewater treatment plant or pumped for export as hazardous waste. • Spare capacity of 2 m height (over 350 m^3) is always maintained in the treated wastewater reservoir. • Most raw materials are in solid form, and any liquids are in small containers (typically up to 2 L). • Spill prevention & control plan (SOP M21310), spill kit in the area & staff training on spill response; spills of solids are swept / vacuumed, whereas spills of liquids are absorbed using absorbents.	The impermeability of various elements of the wastewater treatment plant was certified in 2014 by an independent architect & civil engineer. Certification is repeated every five years.
Spill of raw materials (solvents) used in API production	Permeable strata above water table, rainwater runoff	Land Groundwater Wied Żnuber valley	• Currently stored in the external warehouse (**Figure 11** to **Figure 13**), which has a concreted floor with floor drains leading to the wastewater treatment plant. Most of	• Some temporary storage of solvents outside the bunded area of the external warehouse was noted during the site visit (**Figure 15**). The EPHS Manager has

[6] A pathway only exists if the current mitigation measures fail.

Source	Pathway	Receptor	Mitigation measures	Notes
		Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	this area is covered by a roof. • In the tank farm (**Figure 14**)[7], a new solvent tank is being installed; the tank farm has a concrete floor and bund with a capacity >88,260 L, and has valves that may be opened to discharge clean rainwater to the treated water reservoir. Effluent from the treated water reservoir is tested prior to discharge to sewer.	confirmed that this is a temporary arrangement (one to two days) due to current lack of space in the external warehouse and that these solvents would be used within a day or two. A procedure is being implemented to ensure that spill pallets are in place in such instances. • The impermeability of the tank farm bund (and the pump pit next to the tank farm) was certified in 2014 by an independent architect & civil engineer; testing was carried out by means of a hydrostatic test. Certification is repeated every five years. • Following the installation of the new solvent tank, storage will no longer take place outside the bunded area of the external warehouse.
Spill during production (of raw materials, solvents, APIs in solution)	Permeable strata above water table	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Production occurs indoors; the production facilities have a concrete floor covered by an impermeable resin (**Figure 16**). • Floor drains in the production areas lead to the wastewater treatment plant. • Separate drains are present to collect spills; these lead to a dedicated 4 m^3 reservoir (labelled as *2: process drains reservoir* in **Figure 25**) where the spill can be retained and inspected / tested before a decision is made regarding whether the spill can be treated in the wastewater treatment plant	The impermeability of various elements of the wastewater treatment plant was certified in 2014 by an independent architect & civil engineer. Certification is repeated every five years.

[7] The tank farm has space for eight tanks, however, only two tanks (containing mother liquor waste) are currently installed. Each tank has a capacity of 33,000 L.

Source	Pathway	Receptor	Mitigation measures	Notes
			or pumped for export as hazardous waste. • Spare capacity of 2 m height (over 350 m^3) is always maintained in the treated wastewater reservoir. • Spill prevention & control plan (SOP M21310), spill kit in the area & staff training on spill response.	
Spillage of diesel	Permeable strata above water table, rainwater runoff	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in up to two metal drums inside a bunded container (**Figure 17**); less than 300 L stored in this area at any time. • The generator's diesel tank (900 L) is bunded; the bund capacity has been calculated by the Operator to be 228 L. The filling point is located within the bund.	A new bund will be constructed for the generator tank in August 2017, increasing the containment capacity to at least 990 L.
Spillage of cooling tower chemicals (biocide, continuum AT4505)	Permeable strata above water table, rainwater runoff[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in the bunded external utilities area; the area is connected to large retention pits, which have valves that may be opened to discharge clean rainwater to the treated wastewater reservoir. • Less than 100 L of each of these chemicals is stored at any time.	The impermeability of the external utilities bund was certified in 2014 by an independent architect & civil engineer; the bund was inspected visually and some of the seams were redone. The bund pit was also inspected visually; it is noted that this pit is tiled. Certification is repeated every five years.
Spillage of RO plant chemicals (sodium metabisulfite, sodium hypochlorite)	Permeable strata above water table[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in the RO room (**Figure 18**), which has a concrete floor covered by an impermeable resin. • Floor drains in the RO room lead to a pit with valves that may be opened to allow uncontaminated wash water to drain to the treated wastewater reservoir. • Less than 50 kg of sodium metabisulfite and 2 L of sodium hypochlorite are stored at any time.	

Source	Pathway	Receptor	Mitigation measures	Notes
Spillage of vacuum pump oil	Permeable strata above water table, rainwater runoff[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in the bunded external utilities area; the area is connected to large retention pits, which have valves that may be opened to discharge clean rainwater to the treated wastewater reservoir. • Open drums are placed in a retention pallet within this bund. • The maximum quantity of oil stored is less than 800 L.	The impermeability of the external utilities bund was certified in 2014 by an independent architect & civil engineer; the bund was inspected visually and some of the seams were redone. The bund pit was also inspected visually; it is noted that this pit is tiled. Certification is repeated every five years.
Spillage of wastewater treatment plant chemicals (coagulant, NaOH, H_2SO_4)	Permeable strata above water table, rainwater runoff[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in a tiled bunded area (**Figure 19**) next to the wastewater treatment plant. • The maximum quantity stored is less than 500 L of coagulant, and less than 1 tonne each of NaOH and H_2SO_4.	The impermeability of the bund was certified in 2014 by an independent architect & civil engineer; the bund was inspected visually. Certification is repeated every five years.
Spill of APIs	Permeable strata above water table[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Stored in the finished goods warehouse, which has a concrete floor covered by an impermeable resin. • Floor drains in the warehouse lead to the wastewater treatment plant. • Separate drains are present to collect spills; these lead to a dedicated reservoir (labelled as *2: process drains reservoir* in **Figure 25**) where the spill can be inspected before a decision is made regarding whether the spill can be treated in the wastewater treatment plant or pumped for export as hazardous waste. • Spare capacity of 2 m height (over 350 m^3) is always maintained in the treated	• APIs are solid and would not flow easily if a spill occurs. • The impermeability of various elements of the wastewater treatment plant was certified in 2014 by an independent architect & civil engineer. Certification is repeated every five years.

Source	Pathway	Receptor	Mitigation measures	Notes
			wastewater reservoir. • Spill prevention & control plan (SOP M21310), spill kit in the area & staff training on spill response.	
Spill from high-potency unit	Permeable strata above water table[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Any spills would drain to a drum located within an isolated concreted pit (**Figure 20**). • Spill prevention & control plan (SOP M21310), spill kit in the area & staff training on spill response.	The impermeability of the pit was certified in 2014 by an independent architect & civil engineer; the plant had been newly lined and was inspected visually. Certification is repeated every five years.

Spill of hazardous waste	Permeable strata above water table, rainwater runoff[6]	Land
		Groundwater
		Wied Żnuber valley
		Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)
			• Waste is stored in the following areas:
			  ○ External warehouse (**Figure 11** to **Figure 13**);
			  ○ Outdoor waste area opposite the external warehouse (**Figure 21** and **Figure 22**);
			  ○ ISO tank area (**Figure 23**); and
			  ○ Tank farm (**Figure 14**).
			• The external warehouse has a concreted floor with floor drains leading to the wastewater treatment plant. The warehouse is mostly covered by a roof.
			• The waste area has a concreted floor with floor drains leading to the wastewater treatment plant.
			• The ISO tank area has a concreted floor with floor drains leading to the wastewater treatment plant.
			• The tank farm has a concrete floor and bund with a capacity >88,260 L, and has valves that may be opened to discharge
				The impermeability of the tank farm bund (and the pump pit next to the tank farm) was certified in 2014 by an independent architect & civil engineer; testing was carried out by means of a hydrostatic test. Certification is repeated every five years.

Source	Pathway	Receptor	Mitigation measures	Notes
			clean rainwater to the treated water reservoir. Effluent from the treated water reservoir is tested prior to discharge to the sewer.	
Emissions to air from production (point 1)	Air dispersion (prevailing wind direction); wet precipitation	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Scrubber. • Weekly replacement of scrubber water, pH checks before starting a new process. • Annual VOC emissions monitoring.	The 2015 AER indicates that the plant is compliant with the VOC limit values set by the IPPC permit.
VOCs from solvent / mother liquor tanks (point 2)	Air dispersion (prevailing wind direction); wet precipitation	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	• Emissions are abated using a heat exchanger.	The 2015 AER indicates that 1.4 tonnes of fugitive VOC emissions were released annually; this amounts to 0.6% of the total solvents used in the year (i.e. less than the 5% allowed by the IPPC permit).
HVAC plant exhaust (point 4a)	Air dispersion (prevailing wind direction); wet precipitation	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	HEPA filtration.	• The integrity of the HEPA filters is monitored through a combination of pressure switches (with alarms) and analogue gauges to indicate the status of the filter. • A preventive checking and maintenance programme is also in place.
High-potency lab HVAC exhaust (point 4b)	Air dispersion (prevailing wind direction); wet precipitation	Land Groundwater Wied Żnuber valley	HEPA filtration.	• The integrity of the HEPA filters is monitored through a combination of pressure switches (with alarms) and analogue gauges to indicate the status of

Source	Pathway	Receptor	Mitigation measures	Notes
		Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)		the filter. • A preventive checking and maintenance programme is also in place.
Spill of untreated wastewater (in the underground pipework, or release from the wastewater treatment plant itself)	Permeable strata above water table[6]	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	The impermeability of various elements of the wastewater treatment plant was certified in 2014 by an independent architect & civil engineer; the following elements were inspected: • Three tiled pits / reservoirs (inspected visually), labelled as *1-3* in **Figure 25**; • The treated wastewater reservoir, labelled as *4* in **Figure 25** (tested through hydrostatic testing); and • A lined pit (labelled as *5* in **Figure 25**) next to the treated wastewater reservoir (inspected visually). Certification is repeated every five years.	• It is noted that the tanks where pH adjustment, coagulation and flocculation are carried out consist of welded HDPE tanks at first floor level (these are labelled as *6-8* in **Figure 25**); any leaks would be collected in the homogenisation pit and can therefore be noted quickly. • The pipework leading to the plant is located underground; the Operator has indicated that it is made of plastic and is single-skinned.
Used firefighting water (generated in case of a fire), contaminated with raw materials (including solvents), products (APIs), and hazardous waste	Permeable strata above water table; rainwater runoff	Land Groundwater Wied Żnuber valley Designated cliffs (SPA, SAC, AEI) and garrigue (AEI)	*Measures to prevent uncontrolled discharge of contaminated firefighting water:* • Used firefighting water from the production and internal / external storage areas is collected in the treated wastewater reservoir. • Spare capacity of 2 m height (over 350 m^3) is always maintained in the treated wastewater reservoir (this is checked regularly by the EPHS Manager); the reservoir overflow is pumped to sewer. • Used firefighting water from the high-potency unit is collected inside drums in an isolated pit.	• The impermeability of the treated wastewater reservoir was tested in 2014 (through hydrostatic testing) by an independent architect & civil engineer. Certification is repeated every five years. • The impermeability of the high-potency pit was certified in 2014 by an independent architect & civil engineer; the plant had been newly lined and was inspected visually. Certification is repeated every five years.

Source	Pathway	Receptor	Mitigation measures	Notes
			Measures to reduce the probability / severity of a fire: • Emergency Plan. • Fire detectors (mix of heat and smoke detectors) installed in all indoor areas; automatic fire spinklers are installed outside. • Fire-fighting system including water hydrants, foam and sprinklers, and automatic LPG supply shut-off in the event of a fire in the boiler. • Firefighting water reservoir (**Figure 24**) always kept full (the useful volume for firefighting is greater than 385 m^3, which provides around 1 hour of firefighting water at full flow); this water is not used for other purposes on site. • Training of employees to ensure safe operation. • Storage of flammable substances / waste outdoors.	The impermeability of the firefighting water reservoir was certified in 2014 by an independent architect & civil engineer; the reservoir was inspected visually. Certification is repeated every five years.

Figure 10: Raw materials warehouse

Figure 11: External warehouse

Figure 12: External warehouse

Figure 13: External warehouse

Figure 14: Tank farm

Figure 15: Temporary solvent storage

Figure 16: Production area

Figure 17: Diesel drum inside bunded container

Figure 18: RO room

Figure 19: Wastewater treatment plant chemicals

Figure 20: High potency unit pit

Figure 21: Waste area

Figure 22: Waste area

Figure 23: ISO tanks area

Figure 24: Firefighting water reservoir

Identification of Potential Releases

45. Relevant releases could occur from accidental spillages of the various hazardous substances used and produced on site, namely the raw materials used in API production and associated activities, APIs manufactured on site, and hazardous waste.

46. Air emissions containing VOCs and fine dust (potentially containing APIs) will also be generated from several emission points. Mitigation measures will, however, be in place to reduce air emissions, as described in **Table 10**.

47. Releases could also occur from contaminated wash water, notably that generated from the production areas during the cleaning of the equipment and floors.

48. Used fire-fighting water will also be generated in the event of a fire, which may become contaminated with the hazardous substances and waste stored and handled on site. However, mitigation measures are in place to reduce the probability and severity of a fire, as described in **Table 10**.

Identification of Migration Pathways

49. With the mitigation currently in place, any spill of the raw materials used in API production, spills during production, and waste from the external warehouse, the outdoor waste area opposite it, and the ISO tank area, would be collected in floor drains leading to a dedicated reservoir in the wastewater treatment plant (point *2* in **Figure 25**). The nature of the spill is investigated and a decision is made by the Operator on whether the effluent is to be treated in the wastewater treatment plant, or pumped to a container for export as hazardous waste. It is noted that treated effluent from the wastewater treatment plant is tested, and pumped to sewer only when the Scheme's discharge limits are met.

50. APIs in the finished goods warehouse could potentially follow the same route to the above wastewater reservoir; however, since these are solid they would be more likely to be retained in the warehouse until collected.

51. Any solvents stored temporarily outside the bunded area of the external warehouse will be placed on spill pallets to ensure that spills are contained. Also, this area will no longer be used for storage once the new solvent tank is installed in the tank farm.

52. Additionally, spills of solvents / solvent waste from the tank farm would be retained inside a concrete bund having a capacity larger than 110% of any tank stored within it. Clean rainwater from this area is discharged to the treated water reservoir; the discharge operation requires a valve to be opened using a special wrench (stored in a different area), and is only carried out by authorised staff following visual confirmation that no spills have occurred in the area.

53. Spills in the external utilities area would be fully retained inside the bund and retention pits for this area. Spills of RO plant chemicals would be retained in the pit for the RO room. The pits in these areas may also be opened by authorised

staff, with clean rainwater / wash water being allowed to drain to the treated wastewater reservoir only after it has been confirmed that no spills have occurred.

54. Spills of wastewater treatment plant chemicals would be retained in a tiled bunded area.

55. Spills from the high-potency unit would be collected in a drum located within an isolated concreted pit.

56. Therefore provided the above containment systems are working effectively, there would be no pathway to land and groundwater from these areas. The integrity of several elements of these containment systems has been visually inspected or tested hydrostatically by an independent civil engineer (the elements tested are identified in **Table 10**), and certification is repeated every 5 years. It is noted that the testing did not cover all the containment on site, and the underground pipework is also not tested. However, the Operator plans to have the containment for the external warehouse and the outdoor waste area, as well as the underground pipework linking various storage areas to the wastewater treatment plant, certified by end April 2017.

57. Effluent pathways from the key areas on site are outlined in **Figure 25** (process drains are indicated in light blue).

58. Spills of diesel from either of the two metal drums would be retained inside the bunded container. Spills of up to 228 L from the 900L generator diesel tank would be retained; however, currently the generator tank bund is not able to retain spills beyond this volume. Rainwater could also become contaminated with a spill if the bund is breached, with the rainwater runoff potentially leaving the site and contaminating the road and valley south of the Scheme. However, in August 2017 the operator plans to construct a bund to increase the containment capacity around the generator to at least 990 L.

59. The pathway for air emissions would be air dispersion, particularly in the prevailing wind direction, as well as contamination through precipitation of the pollutants in rainwater[8].

60. In the event of a fire, a dedicated water reservoir will provide fire-fighting water to contain and put out the fire as soon as possible. This reservoir is always kept full and the water is not used for other purposes, to ensure that there is always sufficient water available for fire-fighting purposes. Used extinguishant from the production and storage areas is collected in the treated wastewater reservoir (where a spare capacity of over 350 m^3 is maintained) or, in the case of the high-potency unit, inside drums within an isolated pit. The overflow from the Scheme's wastewater treatment plant leads to the sewer, whereas contaminants

[8] The receptors for such emissions would normally include the air-sensitive receptors located downwind of the Scheme site; however, these are not being considered in this report since the purpose is to assess risks to land and groundwater.

released to sewer would eventually be received by the Water Services Corporation's urban wastewater treatment plant, and be treated before discharge to the sea, and so this pathway, if used, is not expected to lead to land / groundwater contamination.

Identification of Potential Receptors

61. Where a pollutant pathway exists for the scenarios considered, the main receptor is the underlying land. The geology of the site and its immediate surroundings are as shown in **Figure 26**. At the Scheme site, the exposed rock formation is Lower Coralline Limestone.

62. In these scenarios, contaminants could also eventually reach the groundwater. The mean sea level aquifer is the principal hydrogeological feature in the area (**Figure 27**). This aquifer is a lens-shaped water body reaching some 2.5 m above sea level in central Malta and thinning out to zero thickness at the coastline. Since the site is located only around 415 m away from the coast, the groundwater at the Scheme site is expected to be found at a depth of around 55 – 60 m below the land surface, and the groundwater layer would be fairly thin. As a result, even if the land becomes contaminated with a release from the Scheme, significant attenuation of contaminants is expected, considering that there is a considerable depth of rock before the material is able to reach the groundwater, provided there are no direct routes to groundwater (such as fissures and boreholes).

63. The site is located outside the Groundwater Safeguard Zone; however, there are two boreholes used for industrial purposes located within approximately 500 m of the site.[9]

64. The Scheme is also located around 15 m north of the mouth of the Wied Żnuber valley; this watercourse discharges at sea level. This valley includes a maquis habitat that contains the following plant species: *Arundo donax*, *Crataegus monogyna*, *Erica multiflora*, *Ceratonia siliqua*, *Opuntia ficus-indica*. Freshwater pools are also recorded in Wied Żnuber (**Figure 27**).

65. The cliffs located along the coast just south of the site (starting from the southern boundary of the Scheme site) are designated as part of a Special Protected Area (SPA), a Natura2000 Special Area of Conservation (SAC) – Site of International Importance, and scheduled as an Area of Ecological Importance (AEI) (**Figure 28**). The garrigue in these areas is also designated as an AEI. The cliffs making up this part of the SPA / SAC are home to protected seabird breeding colonies, including the Scopoli's and Yelkouan Shearwaters. The blue rock thrush (*il-Merill*), which is a species of conservation importance, also frequents and breeds in the area.

[9] George Cassar (Malta Resources Authority), email dated 15th November 2016.

Figure 25: Surface water and wastewater management

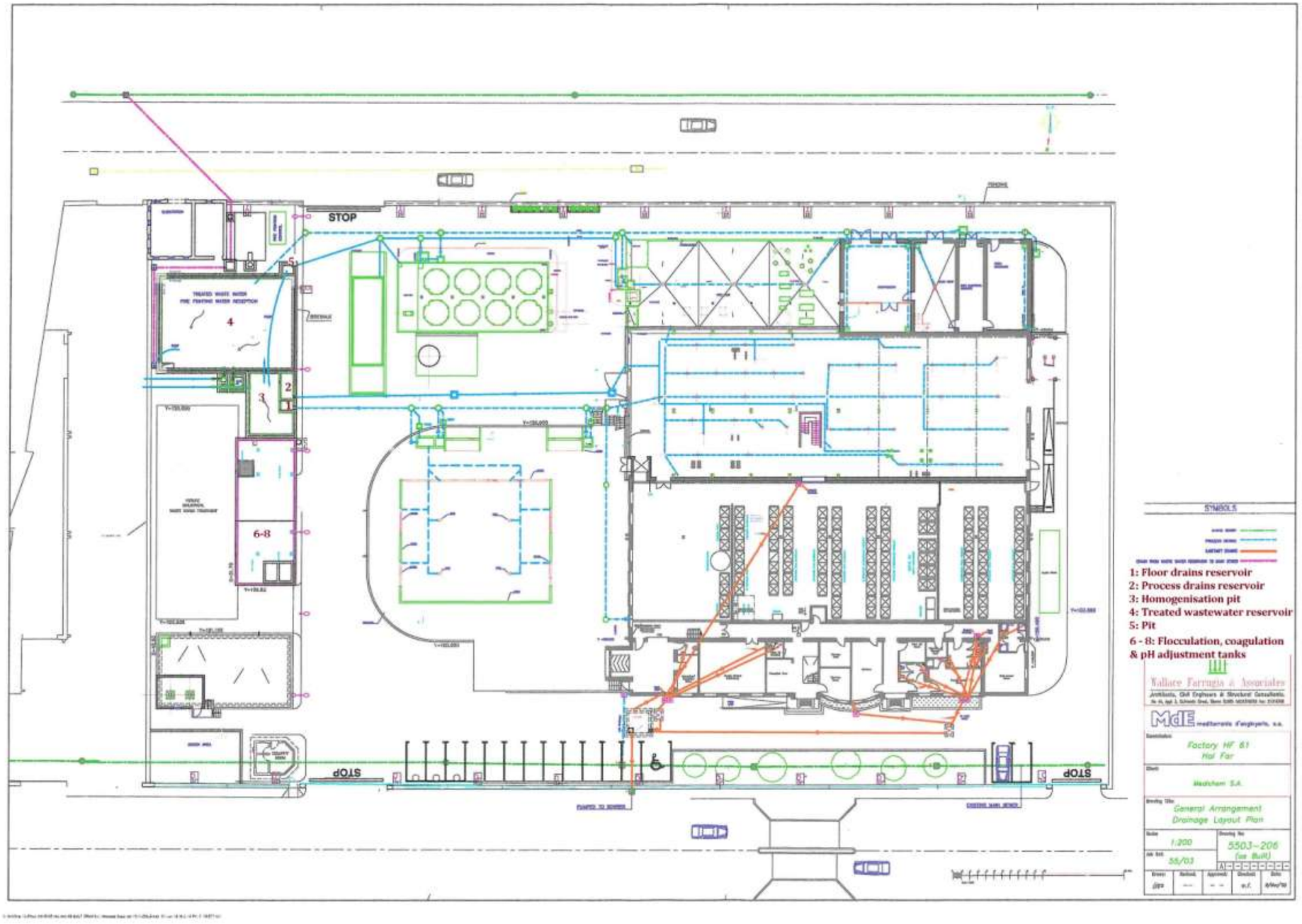


Figure 26: Geology of the Scheme site and its surroundings

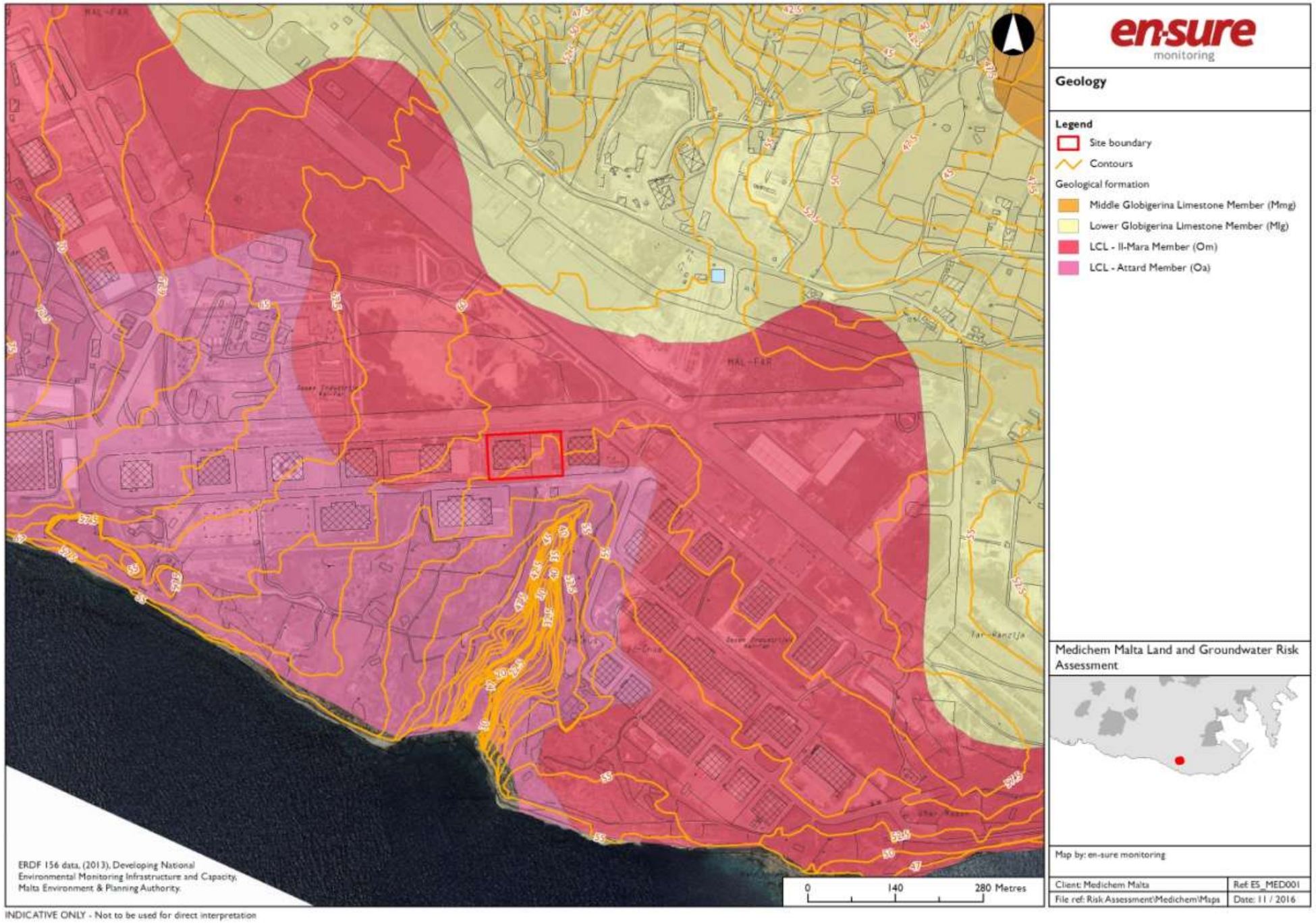
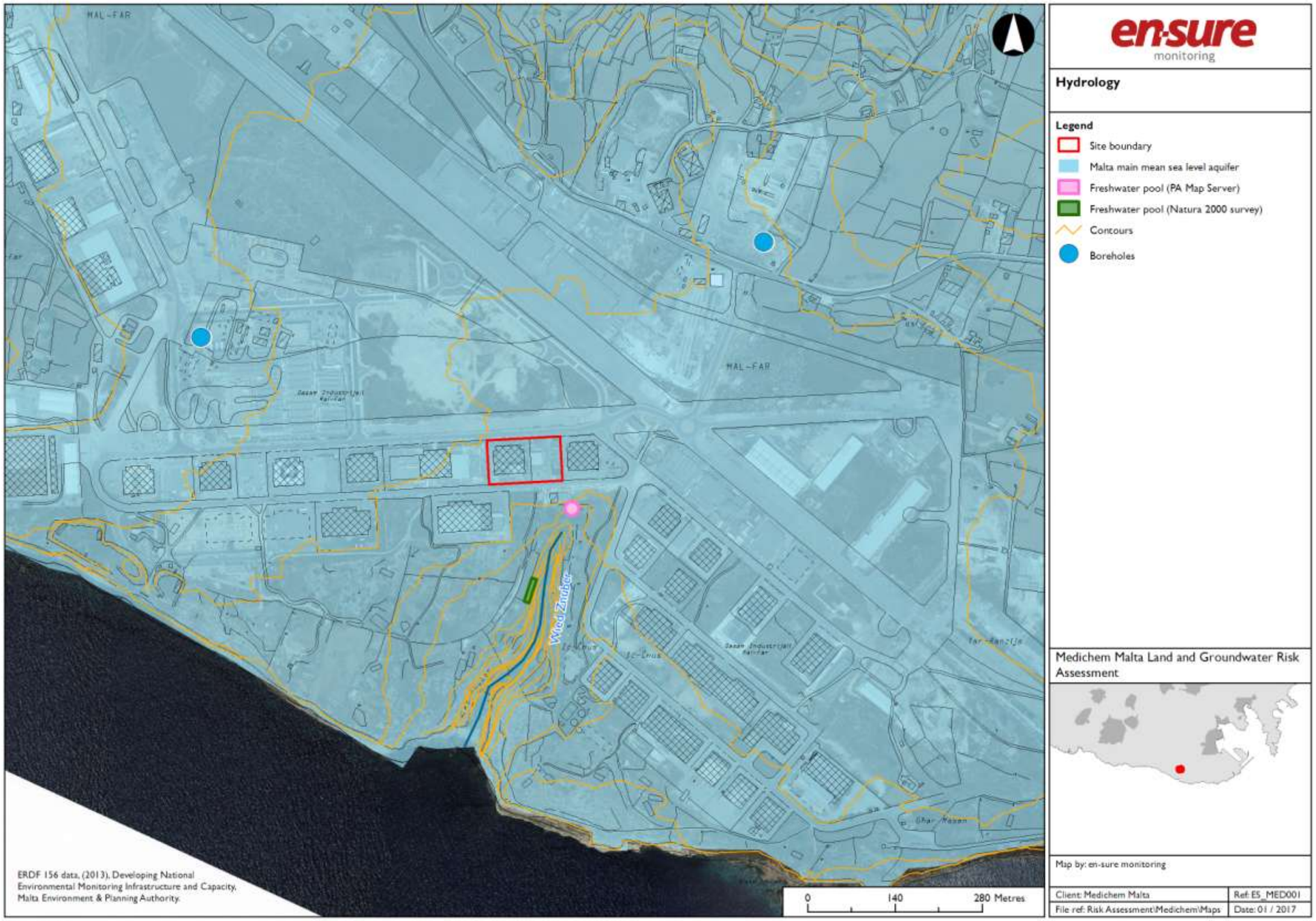
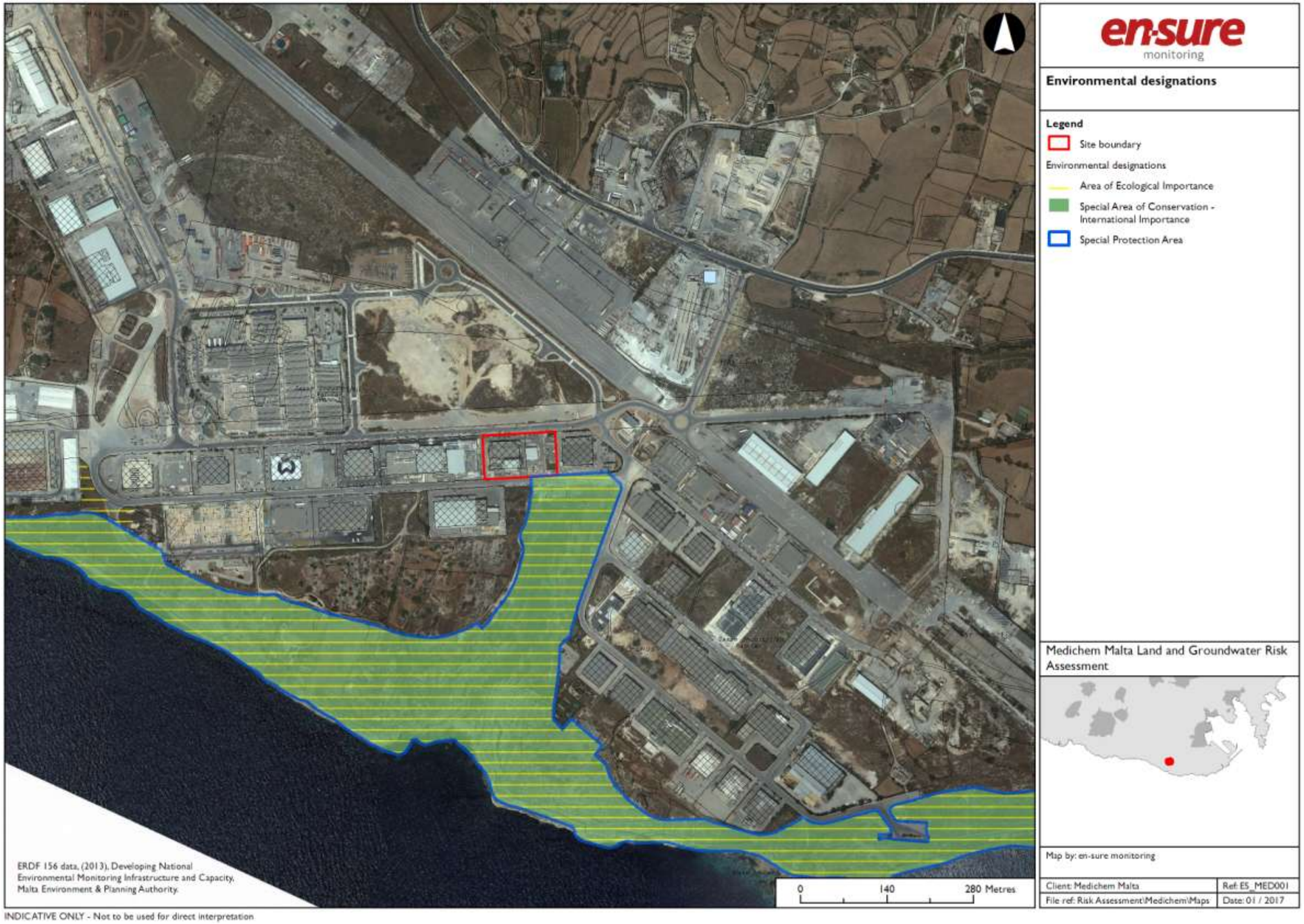


Figure 27: Hydrology of the Scheme site and its surroundings



INDICATIVE ONLY - Not to be used for direct interpretation

Figure 28: Environmental designations around the Scheme site



INDICATIVE ONLY - Not to be used for direct interpretation

Risk Evaluation

66. The risks to land and groundwater have been assessed using the evaluation criteria described earlier.

67. The risks associated with both the current mitigation scenario and the scenario that includes the further planned mitigation measures are evaluated. It should be noted that the Scheme proposes to include all the mitigation measures described.

Current Mitigation

68. **Table 11** presents risk levels for each source in the current scenario.

Table 11: Risk levels (current mitigation)

Source	Environmental consequence	Likelihood of consequence	Resultant risk level
Spill of raw materials during storage in raw material warehouse	No pollutant linkage		None
Spill of solvents during storage in external warehouse (bunded area)	Moderate	Unlikely	Moderate
Spill of solvents during storage in external warehouse (temporary storage outside bunded area)	Moderate	Occasional	High
Spill of solvents during storage in tank farm	No pollutant linkage		None
Spill during production	No pollutant linkage		None
Spill of diesel from metal drums	No pollutant linkage		None
Spill of diesel from generator tank	Moderate	Unlikely	Moderate
Spill of cooling tower chemicals	No pollutant linkage		None
Spill of RO plant chemicals	No pollutant linkage		None
Spill of vacuum pump oil	No pollutant linkage		None
Spill of wastewater treatment plant chemicals	No pollutant linkage		None
Spill of APIs in finished goods warehouse	No pollutant linkage		None
Spill from high-potency unit	No pollutant linkage		None
Spill of hazardous waste from external warehouse	Moderate	Unlikely	Moderate
Spill of hazardous waste from outdoor waste area	Moderate	Unlikely	Moderate
Spill of hazardous waste from ISO tank area	Moderate	Unlikely	Moderate
Spill of hazardous waste from tank farm	No pollutant linkage		None
Emissions to air from production (point 1)	Insignificant	Almost certain	Low
VOC emissions from solvent / mother liquor tanks (point 2)	Insignificant	Almost certain	Low
Emissions to air from HVAC plant exhaust (point 4a)	Insignificant	Almost certain	Low
Emissions to air from high-potency lab HVAC exhaust (point 4b)	Insignificant	Almost certain	Low
Leak of untreated production effluent from the pipework leading to the wastewater treatment plant	Minor	Occasional	Moderate

Source	Environmental consequence	Likelihood of consequence	Resultant risk level
Leak of solvents / hazardous waste (when spilt) from the pipework connecting the storage areas to the wastewater treatment plant	Minor	Occasional	Moderate
Leak of untreated wastewater from the wastewater treatment plant	No pollutant linkage		None
Used fire-fighting water (generated in case of a fire), contaminated with raw materials (including solvents), products (APIs), and hazardous waste	No pollutant linkage		None

69. With regard to spills in the raw materials warehouse and spills during production, considering the level of containment in these areas (concrete floor covered by an impermeable resin), the possibility of a pollutant linkage is removed; therefore, this scenario would not present a risk to land / groundwater.

70. A spill of solvents / hazardous waste during storage in the external warehouse would require a failure of the containment system in order to have any environmental effect; since the impermeability of the concreted floor in this area is not checked, this scenario has been classified as unlikely. The environmental consequences of a spill that reaches land / groundwater are classified as moderate, since while the materials stored are hazardous, the substances / waste are stored in 250 L drums or 1 m^3 IBCs; therefore, materials are unlikely to be released in large quantities. The environmental consequences of a spill from the temporary storage of solvents outside this area would also be moderate; however, since this area is not contained the likelihood of such an incident has been classified as occasional.

71. In order to have an environmental consequence, a solvent / waste spill in the tank farm would require a failure of the concrete bund. The bund has a capacity that greatly exceeds 110% of the size of the tanks stored within it, and the bund was tested in 2014 (with testing to be repeated every five years), therefore there is no pollutant linkage.

72. A spill of diesel from the metal drums would also be fully contained, thus removing the pollutant linkage. However, there is the possibility of a diesel spill (of up to around 700 L) from the generator tank, since the bunding capacity here is limited. The environmental consequences of such a spill could be moderate, especially considering the close proximity of the Scheme site to sensitive natural areas. However, the possibility of a significant spill that leaves the site undetected is classified as unlikely.

73. There is also no pollutant linkage in the event of a spill of cooling tower chemicals and vacuum pump oil in the bunded external utilities area; it is noted that the bund is periodically inspected.

74. The pollutant linkage is similarly removed with regard to a spill of RO plant chemicals, wastewater treatment plant chemicals, APIs stored in the finished goods warehouse, and substances from the high-potency unit.

75. A spill of hazardous waste during storage in the outdoor waste area and the ISO tank area would require a failure of the containment system in order to have an environmental effect; since the impermeability of the concreted floor in these areas is not checked, this scenario has been classified as unlikely. The environmental consequences of a spill that reaches land / groundwater are classified as moderate, since the waste is stored in 1 m^3 IBCs, therefore releases of large quantities of hazardous waste are unlikely.

76. Emissions to air are not expected to have a significant impact on land or groundwater, due to the abatement and monitoring systems in place. It is noted that emissions are compliant with the limit values in the IPPC permit. Such emissions are routinely generated, and therefore the likelihood of this scenario has been classified as almost certain.

77. A leak of effluent from the pipework connecting the production areas to the wastewater treatment plant could occur occasionally, since the pipework is single-skinned and is not inspected or certified. However, the environmental consequences of such a leak are likely to be minor since such effluent would only be lightly contaminated.

78. Leaks of solvents / hazardous waste could also occur in the underground pipework linking various storage areas to the wastewater treatment plant. Such leaks would require a failure of both the storage container and the pipework, and therefore can be classified as occasional. The main areas where such spills could be generated are the external warehouse, the outdoor waste area, and the ISO tank area (since spills from the raw materials warehouse and the finished goods warehouse would mostly be of solids and are unlikely to travel via the underground pipes). The environmental consequences are considered to be minor, since even though 1 m^3 may be spilt if a single container is breached, only a small proportion would be released from the pipes (e.g. through a crack in the joints).

79. Since the integrity of the wastewater treatment plant is routinely inspected and certified, there is no pollutant linkage from this area.

80. Similarly, since all used extinguishant is collected and the collection systems for used extinguishant are all inspected and certified periodically, the pollutant linkages for this scenario are removed.

Further Mitigation

81. **Table 12** presents risk levels for each source in the scenario when the further planned mitigation measures are in place.

Table 12: Risk levels with further mitigation

Source	Environmental consequence	Likelihood of consequence	Resultant risk level
Spill of raw materials during storage in raw material warehouse	No pollutant linkage		None
Spill of solvents during storage in external warehouse	No pollutant linkage		None
Spill of solvents during storage in external warehouse (temporary storage outside bunded area)	No pollutant linkage		None
Spill of solvents during storage in tank farm	No pollutant linkage		None
Spill during production	No pollutant linkage		None
Spill of diesel from metal drums	No pollutant linkage		None
Spill of diesel from generator tank	No pollutant linkage		None
Spill of cooling tower chemicals	No pollutant linkage		None
Spill of RO plant chemicals	No pollutant linkage		None
Spill of vacuum pump oil	No pollutant linkage		None
Spill of wastewater treatment plant chemicals	No pollutant linkage		None
Spill of APIs in finished goods warehouse	No pollutant linkage		None
Spill from high-potency unit	No pollutant linkage		None
Spill of hazardous waste from external warehouse	No pollutant linkage		None
Spill of hazardous waste from outdoor waste area	No pollutant linkage		None
Spill of hazardous waste from ISO tank area	No pollutant linkage		None
Spill of hazardous waste from tank farm	No pollutant linkage		None
Emissions to air from production (point 1)	Insignificant	Almost certain	Low
VOC emissions from solvent / mother liquor tanks (point 2)	Insignificant	Almost certain	Low
Emissions to air from HVAC plant exhaust (point 4a)	Insignificant	Almost certain	Low
Emissions to air from high-potency lab HVAC exhaust (point 4b)	Insignificant	Almost certain	Low
Leak of untreated production effluent from the pipework leading to the wastewater treatment plant	Minor	Unlikely	Low
Leak of solvents / hazardous waste (when spilt) from the pipework connecting the storage areas to the wastewater treatment plant	Minor	Unlikely	Low
Leak of untreated wastewater from the wastewater treatment plant	No pollutant linkage		None
Used fire-fighting water (generated in case of a fire), contaminated with raw materials (including solvents), products (APIs), and hazardous waste	No pollutant linkage		None

82. Once the external warehouse containment is certified, the pollutant linkage is removed and the resultant risk is also removed. With regard to the temporary

storage of solvents outside this area, the pollutant linkage here will also be removed once spill pallets start being used; moreover, this area will shortly no longer be used for storage since the storage capacity in the tank farm is being increased with the installation of a new solvent tank.

83. The increase in the containment capacity for the generator diesel tank and certification of the new bund would also remove the pollutant linkage in the event of a spill from this tank.

84. The operator also plans to certify the containment for the external warehouse, the outdoor waste area, and the ISO tank area by end April 2017, thus also removing the migration pathway and hence the pollutant linkage.

85. The integrity of the underground pipework linking various storage areas to the wastewater treatment plant will also be certified by end April 2017; this reduces the possibility of failure (of both the storage container and the pipework at the same time) to unlikely and hence the risk from these scenarios to low.

Conclusion and Recommendations

86. In the current scenario, risks to land and groundwater from the Scheme are considered to range from none to high.

87. The further planned mitigation will, however, completely remove pollutant linkages from several areas, namely the external warehouse, the generator diesel tank, the outdoor waste area and the ISO tank area, and will reduce the remaining risks to land and groundwater to low.

88. As a result, baseline land and groundwater monitoring is not considered necessary, provided that the further planned mitigation measures (particularly the certification of the remaining containment systems and underground pipework, the increase in bunding capacity for the generator's diesel tank, and the increase in the storage capacity in the tank farm to remove the temporary storage of solvents outside the external warehouse) are implemented as soon as possible. It is noted that certification is planned for not later than April 2017, the bunding increase is planned for August 2017, and that a new solvent tank is currently being installed in the tank farm.

89. It is recommended that the risk assessment be reviewed in future if new categories of relevant hazardous substances / waste are proposed to be used or produced in significant quantities, if monitoring reveals that the effectiveness of the mitigation measures is reduced, or if additional activities are proposed / implemented that could present a risk of contamination of land or groundwater.