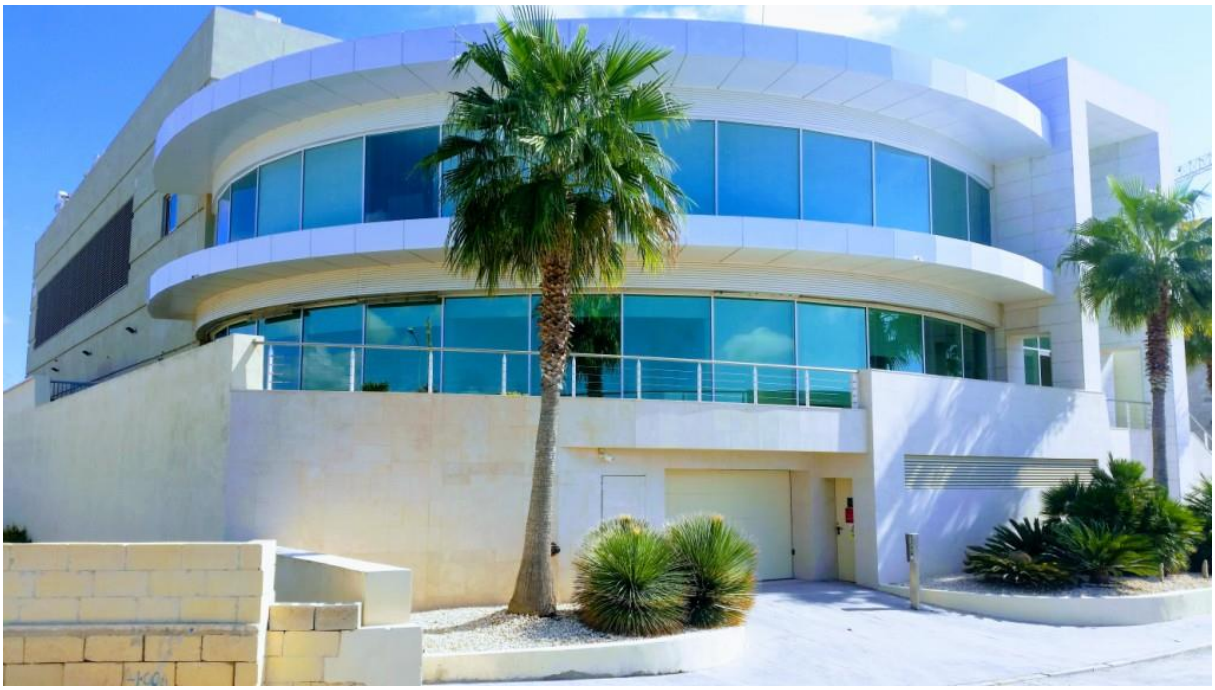
STERLING CHEMICAL MALTA LTD, HAL FAR

APPLICATION FOR VARIATION AND RENEWAL OF IPPC PERMIT

VOLUME 3: ADDENDUM 3 TO LAND AND GROUNDWATER RISK ASSESSMENT



Version 1: February 2021

Report Reference:

En-Sure Ltd, 2021. Sterling Chemical Malta Ltd, Hal Far. Application for Variation and Renewal of IPPC Permit: Volume 3: Addendum 3 to Land and Groundwater Risk Assessment (Version: 3). San Gwann, February 2021; vi + 20 pp. + 1 Appendix.

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Quality Assurance

Sterling Chemical Malta Ltd, Hal Far
Application for Variation and Renewal of IPPC Permit: Volume 3
February 2021

Report for: Sterling Chemical Malta Ltd

Revision Schedule

Rev	Date	Details	Prepared by	Reviewed by	Approved by
00	Feb. 2021	Submission to client	**Rachel Decelis** Senior Environmental Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director

File ref: N:_Active Projects\Environmental Permitting\ES_STG010 - Sterling variation waste storage\IPPC application\Vol 3 - Land & groundwater risk assessment.docx

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ADDENDUM 3 TO LAND AND GROUNDWATER RISK ASSESSMENT

Introduction

1. En-Sure Ltd was commissioned by Sterling Chemical Malta Ltd, herein referred to as 'the Operator', to prepare an application for variation of the Integrated Pollution Prevention and Control (IPPC) permit for the Sterling Chemical Malta Ltd facility.

2. The facility comprises a factory for the manufacture of Active Pharmaceutical Ingredients (APIs). The site is located at HF 50, HF 51 and HF53, Hal Far Industrial Estate (as shown in **Figure 1**).

3. The proposed variations comprise the commissioning of a warehouse for waste storage, and the addition of new emission points to air from production areas and laboratory fume hoods / cabinets.

4. A Land and Groundwater Risk Assessment[1] was prepared for the facility in 2015, to cover the activities permitted at that time; that report is herein referred to as the 'original' risk assessment. Two Addenda were subsequently prepared:

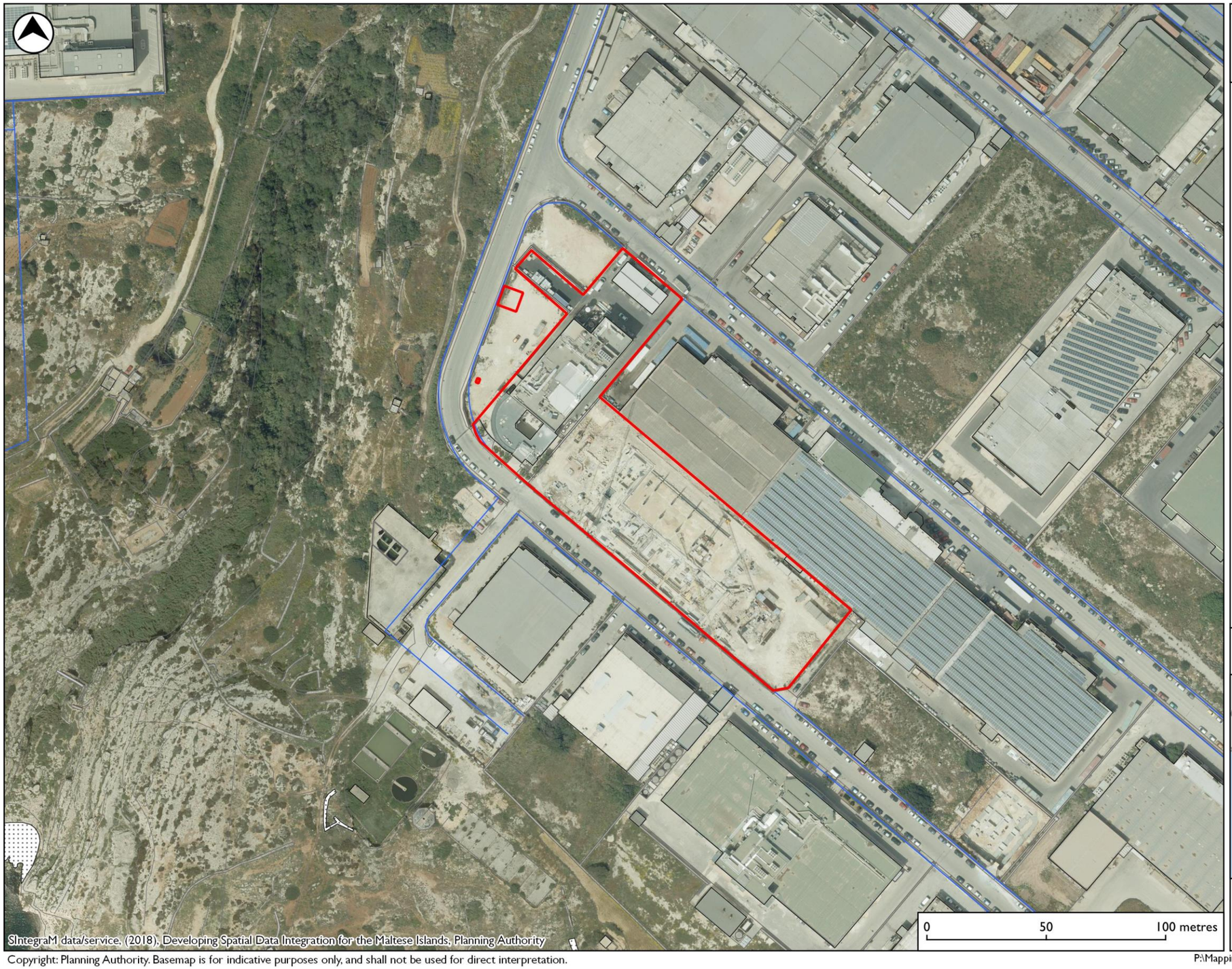
    - Addendum 1[2] covered variations including a micronisation facility, new reactors and cold rooms, a new temporary waste storage area, and a new LPG tank; and

    - Addendum 2[3] covered cover an extension to include the HF53 block, including the operation of an R&D pilot plant, laboratories and other associated activities and utilities.

5. The current Addendum (Addendum 3) covers the operation of the proposed variations, and uses the same methodology as in the original risk assessment. For ease of reference, the risk assessment criteria are included as **Appendix 1**. Since there is no new land uptake envisaged, a description of the site history and the surrounding land uses is not repeated in this document.

[1] En-Sure Ltd, 2015. *Sterling Chemical Malta Ltd, Hal Far: Land and Groundwater Risk Assessment* (Version 1). San Ġwann, December 2015; iv + 41 pp. + 3 Appendices.
[2] En-Sure Ltd, 2018. *Sterling Chemical Malta Ltd, Hal Far. Application for Variation of IPPC Permit: Volume 3: Addendum 1 to Land and Groundwater Risk Assessment* (Version: 2). San Gwann, August 2018; vi + 28 pp. + 1 Appendix.
[3] En-Sure Ltd, 2019. *Sterling Chemical Malta Ltd, Hal Far. Application for Variation and Renewal of IPPC Permit: Volume 3: Addendum 2 to Land and Groundwater Risk Assessment* (Version: 3). San Gwann, August 2019; vi + 31 pp.

Figure 1: Site location



Location of site

Legend

Site boundary

IPPC variation application for Sterling Chemical Malta Ltd

Map by:

Client: Sterling Chemical Ltd
Ref: ES STG010
Date: 11 / 2020

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Description of the Variations

6. As mentioned, the proposed variations comprise a warehouse for waste storage, and the addition of new emission points to air from production areas and laboratory fume hoods / cabinets.

7. A detailed description of these variations is included in **Volume 2** of the IPPC application, notably in Section C2.2.

8. The following subsections summarise the aspects of these proposals that are relevant to the contamination of land and groundwater, and the associated mitigation.

Waste Warehouse

9. The location of the warehouse is marked in red in **Figure 2**. The warehouse will be used to store non-flammable liquids (such as acids, washing liquids, mother liquors and solvents), which are already generated by the existing operations. No new waste types are envisaged. Additionally, the quantities of waste generated from the facility will not change significantly as a result of the proposed variations.

10. Waste will be stored in appropriate labelled containers (such as drums and intermediate bulk containers, IBCs) and stacked on shelves.

11. The maximum quantity of waste stored in the warehouse will be 100 m^3. Any spills would be collected by stainless steel gutters around the internal perimeter, draining to the existing 57 m^3 'water washing reservoir' at the northeastern corner of the HF 53 block.

New Emission Points to Air

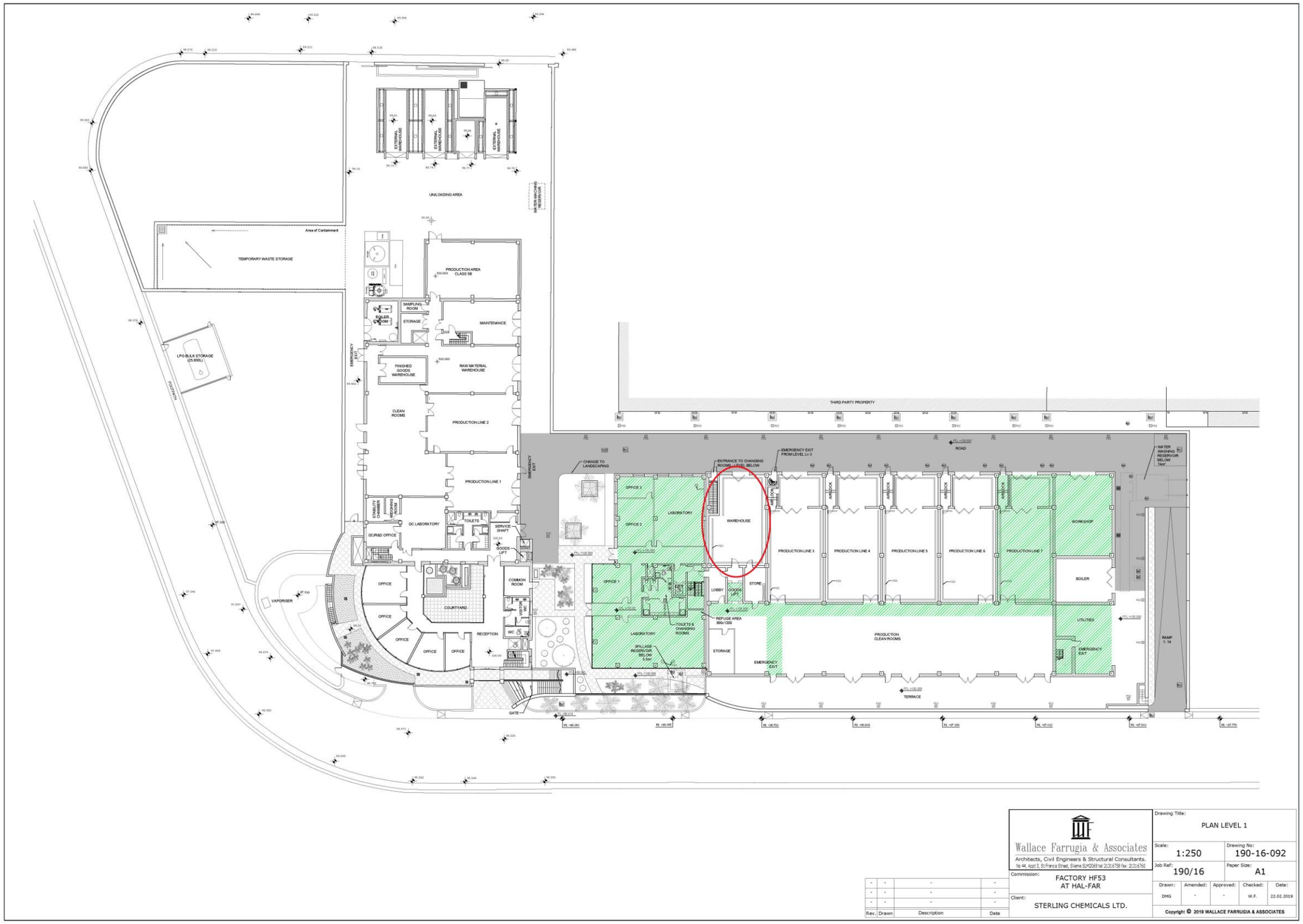
12. The proposed variations include the addition of new emission points to air, as shown in **Table 1**, which also summarises the abatement applicable to each emission point. It is noted that very small quantities of chemicals are handled in the laboratories (corresponding to emission points EM4C-E, EM8A-D, and EM10B-D).

Table 1: New emission points to air

Ref.	Source	Abatement
EM2	HVAC (General ventilation and air-conditioning) – HF 51 block	Fabric filter
EM3A	HVAC Production Line 2 clean rooms	HEPA filter (HF1)
EM3B	HVAC Production Line 1 clean rooms	HEPA filter (HF2)
EM3C	Micronisation plant clean rooms	HEPA filter (HF3)
EM4C	Microniser lab fume hoods	Carbon filter
EM4D	Microniser lab fume hoods	Carbon filter
EM4E	Microniser lab fume hoods	Carbon filter
EM8A	AMS (Quality Control) lab fume hoods	Carbon filter
EM8B	AMS (Quality Control) lab fume hoods	Carbon filter
EM8C	AMS (Quality Control) lab fume hoods	Carbon filter
EM8D	AMS (Quality Control) lab cabinet and localised hoods	Carbon filter

Ref.	Source	Abatement
EM10B	R&D lab fume hoods	Carbon filter
EM10C	R&D lab fume hoods	Carbon filter
EM10D	R&D lab fume hoods	Carbon filter

Figure 2: Layout of the facility (Level 1)



The location of the waste warehouse is circled in red.

Fire Prevention and Response

13. The existing 600 m^3 reservoir on the HF 51 block will continue to be reserved exclusively for firefighting of the entire site. This is kept full at all times, and a level meter with alarm is installed for this purpose. This volume is able to provide up to 150 minutes of firefighting water.

14. The waste warehouse will include a break glass manual call point, an internal fire sounder and a flashing beacon as alarm systems.

15. A Class ABC dry chemical fire extinguisher will also be installed in the waste warehouse. It is noted that if used, such extinguishants do not flow easily, and would therefore mostly be retained in the warehouse itself (although a proportion could flow through the gutters towards the water washing reservoir). There will be no sprinklers or water-based firefighting systems in this area.

Relevant Hazardous Substances and Waste

16. The main contaminant types associated with the proposed variations, and their potential relevance to land / groundwater contamination are presented in **Table 2**.

Table 2: Contaminants and relevance to land / groundwater contamination

Proposed variation	Contaminant types	Relevance	Justification
Waste warehouse	Hazardous waste (e.g. acids, washing liquids, mother liquors, solvents)	Relevant	Hazardous waste in liquid form or solution; washwater from floor cleaning could also be contaminated with these substances.
Emissions from production areas – general ventilation (EM2) and clean rooms (EM3A-3C)	Solvents (usually non-flammable), reagents, APIs	Relevant	• Without mitigation, emissions to air may be released and eventually contaminate land. • Emissions could also dissolve in washwater during floor cleaning, and may also contaminate used firefighting water.
Laboratory fume hoods / cabinets (EM4C-E, EM8A-D, and EM10B-D)	Various chemicals used for testing	Not relevant	Stored and handled in very small-scale quantities (1 to 2.5 L bottles each).
	Products (APIs) undergoing testing	Not relevant	Handled in very small quantities.

Risk Assessment

Overview

17. The risk assessment methodology is based in the identification and evaluation of source-pathway-receptor linkages, as described in the original risk assessment.

18. **Table 3** summarises potential sources of pollution associated with the proposed variations, and the respective pathway to the relevant receptors. The generation of used extinguishant in the event of a fire has also been considered.

19. **Table 3** also includes the mitigation measures that will be adopted to mitigate such risks, distinguishing between fixed construction elements incorporated by the proposed variations and operational / procedural mitigation measures. It is to be noted that all the mitigation measures in the Table will be implemented.

Table 3: Pollution pathway identification and mitigation measures

Source	Pathway	Receptor	Mitigation measures	
			Construction mitigation measures	Operational mitigation measures
Spill from waste warehouse	Direct contamination; permeable strata above water table[4]; used washwater	• Land • Groundwater	• Underlying impermeable concrete layer • Gutters leading to a 57 m^3 concreted water washing reservoir	• Alarm on reservoir (to ensure no overfilling) • Certification of containment systems as required by IPPC permit • Spill kits, and staff training
Emissions to air from production areas – general ventilation (EM2)	Air dispersion (prevailing wind direction); wet / dry deposition	• Land • Groundwater	-	• Fabric filter • Local extraction used if containers are opened, emissions directed to scrubber • Emissions monitoring as required by IPPC permit • Replacement of filter as per maintenance schedule
Emissions to air from production areas – clean rooms (EM3A-C)	Air dispersion (prevailing wind direction); wet / dry deposition	• Land • Groundwater	-	• HEPA filters • Local extraction used if containers are opened; such emissions are directed to scrubber in production lines 1 and 2, and to a HEPA filter followed by a scrubber in the micronisation plant clean rooms • Emissions monitoring as required by IPPC permit • Differential pressure device to monitor filter condition • Replacement of filters as per maintenance schedule

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

Source	Pathway	Receptor	Mitigation measures	
			Construction mitigation measures	**Operational mitigation measures**
Release of used extinguishant from the waste warehouse (generated in case of a fire), contaminated with hazardous waste	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater	• Rainwater reservoir with 600 m^3 of water (150 minutes) dedicated to firefighting; level meter with alarm (this reduces the risk of fire elsewhere on site spreading to the waste warehouse) • Underlying impermeable concrete layer • Gutters leading to a 57 m^3 concreted water washing reservoir	• Emergency fire procedures • Break glass manual call point, internal fire sounder and flashing beacon as fire alarm systems in the waste warehouse • Class ABC dry chemical fire extinguisher (no water is proposed in the waste warehouse) • Training of personnel in fire prevention and basic fire fighting

Identification of Potential Releases

20. Relevant releases could occur from an accidental spill of the waste stored in the warehouse, which may also contaminated washwater used for floor washing.

21. Air emissions containing primarily volatile organic compounds (VOCs) and / or APIs are also generated from the production areas. However, mitigation measures will be in place to reduce air emissions, as described in **Table 3**.

22. Used extinguishant would also be generated in the event of a fire at the waste warehouse, which may become contaminated with hazardous substances.

Identification of Migration Pathways

23. In the absence of mitigation (such as containment), spills and leaks could contaminate the land directly, and could potentially also reach the groundwater through any permeable rock strata underlying the site, or through direct pathways such as fissures.

20. Certain spills could also contaminate rainwater reaching the site, resulting in potential on-site and off-site contamination of land (and eventually groundwater) through rainwater runoff. In the unmitigated scenario, used extinguishant could similarly contaminate land and groundwater.

22. The principal pathway for air emissions would be air dispersion, particularly in the prevailing wind direction; the prevailing wind locally is from the northwest.

24. However, a number of mitigation measures will be in place on site to prevent the migration of contaminants towards land and groundwater, as described earlier, and in **Table 3**.

Identification of Potential Receptors

25. In the scenario without mitigation, in the event of a spill or leak, the first receptor is the underlying land. The geology of the site and its immediate surroundings are as shown in **Figure 3**. At the site, the exposed rock formation is Lower Coralline Limestone.

26. Contaminants could also reach the groundwater in the unmitigated scenario. The mean sea level aquifer is the principal hydrogeological feature in the area (**Figure 4**). This aquifer is a lens-shaped water body reaching some 3 m above sea level in central Malta and thinning out to zero thickness at the coastline. Since the site is located close to the coast, the groundwater at the site is expected to be found at a depth of around 55 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 site and provided there are no direct routes to groundwater (such as fissures), significant attenuation of contaminants is expected, considering that there is a considerable depth of rock before the material is able to reach the groundwater.

27. The site is located outside the Groundwater Safeguard Zone, and there are no private or public groundwater boreholes located within 400 m of the site.[5]

28. The facility is also located around 12 m from the valley sides of Wied Żnuber, which discharges surface water at sea level. This valley includes a maquis habitat that contains the following plant species: *Arundo donax*, *Crataegus monogyna*, *Erica multiflora*, *Ceratonia siliqua*, and *Opuntia ficus-indica*.

29. The cliffs located along the coast just south / southeast of the 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), as shown in **Figure 5**. 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.

[5] George Cassar (Malta Resources Authority), email dated 9th November 2015.

Figure 3: Geology of the site and its surroundings

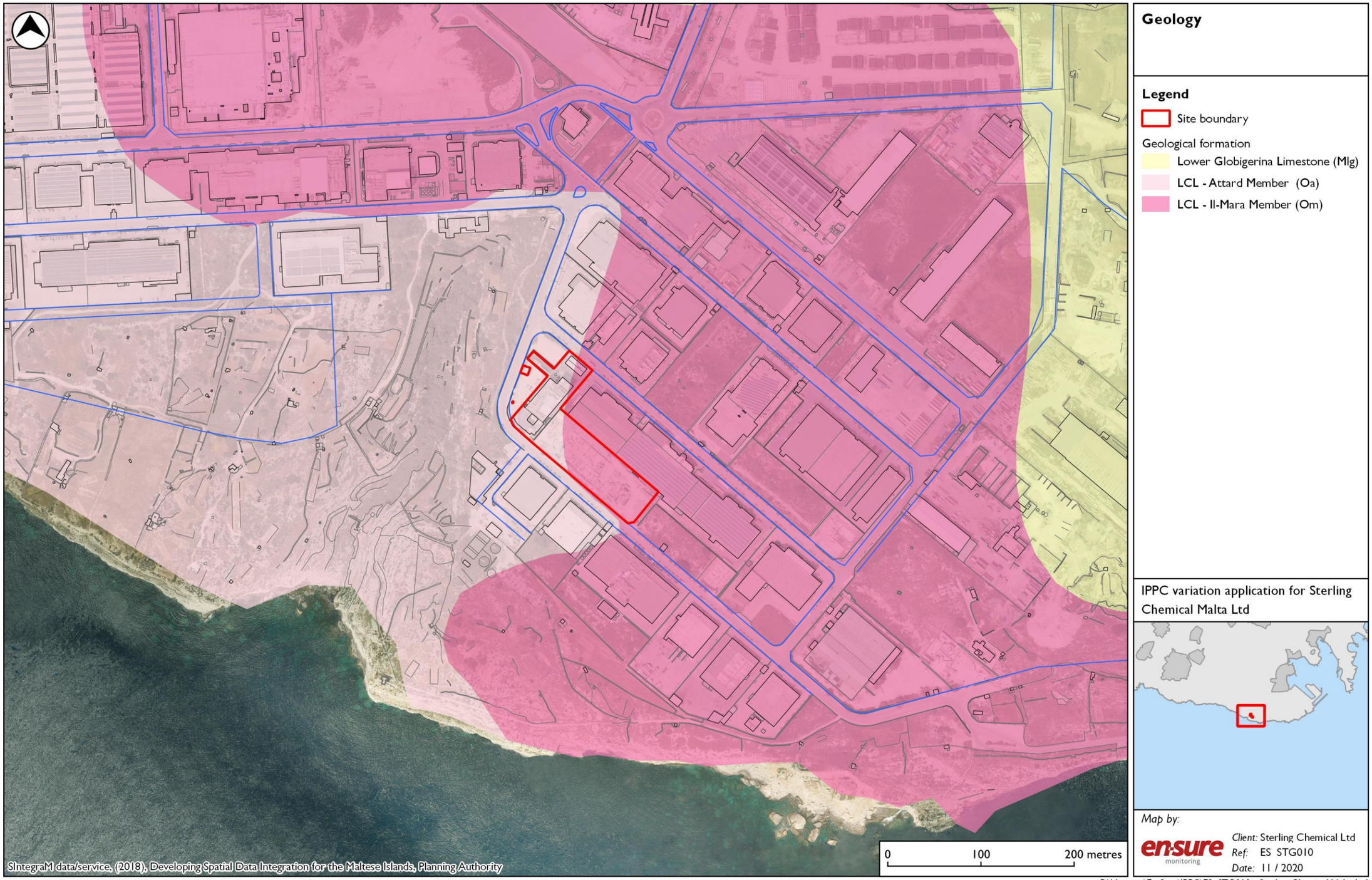


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Figure 4: Hydrology of the site and its surroundings

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Figure 5: Environmental designations

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Risk Evaluation

30. The risks to land and groundwater have been assessed using the evaluation criteria described in the original risk assessment. The risks associated with both the unmitigated and mitigated scenarios are evaluated. However, it should be noted that the proposed variations envisage including all of the mitigation measures described.

Without Mitigation

31. **Table 5** presents the risk levels for each source without the implementation of any mitigation measures.

Table 4: Risk levels (without mitigation)

Source	Environmental consequences	Likelihood of consequence	Resultant risk level
Spill from waste warehouse	Minor	Likely	Moderate
Emissions to air from production areas – general ventilation (EM2)	Minor	Almost certain	Moderate
Emissions to air from production areas – clean rooms (EM3A-C)	Minor	Almost certain	Moderate
Release of used contaminated extinguishant from the waste warehouse	Minor	Occasional	Moderate

32. The likelihood of an accidental spill in the waste warehouse has been classified as likely without precautions. However, such spills are likely to be small (up to 1 m^3 if an entire IBC is spilt), and therefore have minor environmental consequences.

33. In the scenario without mitigation, emissions to air would be routinely generated during transfer activities in the production areas; these could be released to the surroundings, although there will be some dispersal before these emissions reach the land. However, given that the emissions related to the new emission points EM2 and EM3A-C are only related to transfer activities, the quantity of pollutants released and consequent environmental effects have been classified as minor.

34. It is considered that runoff of used extinguishant from the waste warehouse could result in minor environmental consequences if the used extinguishant is contaminated with hazardous waste from the waste warehouse and if it spreads beyond the site (especially if water is used as an extinguishant, which flows easily). Without mitigation, taking into account the flammability and quantity of the substances to be stored (not only at the waste warehouse but also at the rest of the facility), it is considered that a fire may occur occasionally.

With Mitigation

35. **Table 5** presents risk levels for each source with the implementation of the proposed mitigation measures.

Table 5: Risk levels (with mitigation)

Source	Environmental consequence	Likelihood of consequence	Resultant risk level
Spill from waste warehouse	No pollutant linkage		None
Emissions to air from production areas – general ventilation (EM2)	Insignificant	Almost certain	Low
Emissions to air from production areas – clean rooms (EM3A-C)	Insignificant	Almost certain	Low
Release of used contaminated extinguishant from the waste warehouse	No pollutant linkage		None

36. Since the waste warehouse includes concreted containment, which is periodically certified for impermeability, the pollutant linkage in case of a spill is removed. Similarly, the pollutant linkage related to the release of used extinguishant is also removed.

37. Emissions to air from the production areas included in the proposed variations are not expected to have a significant impact on the environment, due to the abatement systems that will be in place. Such emissions are routinely generated, and therefore the likelihood of this scenario has still been classified as almost certain.

Conclusion and Recommendations

38. As a result of the mitigation measures envisaged to be implemented, notably containment and abatement systems, risks to land and groundwater from the proposed variations have been reduced to low, with no pollutant linkage identified in two scenarios.

39. As a result, baseline land and groundwater monitoring is not considered necessary, provided that the identified mitigation measures are implemented.

40. It is also recommended that a monitoring programme be set up to ensure that the mitigation measures are implemented and functioning effectively.

41. Finally, 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 that could present a risk of contamination of land or groundwater.

Appendix 1: Risk assessment criteria

42. **Table A-1** presents criteria for assessing environmental consequences, whereas **Table A-2** presents criteria for assessing the likelihood of the event occurring.

Table A-1: 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 A-2: 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

43. The overall risk level is then determined by combining the two factors, using the matrix in **Table A-3**.

Table A-3: 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	