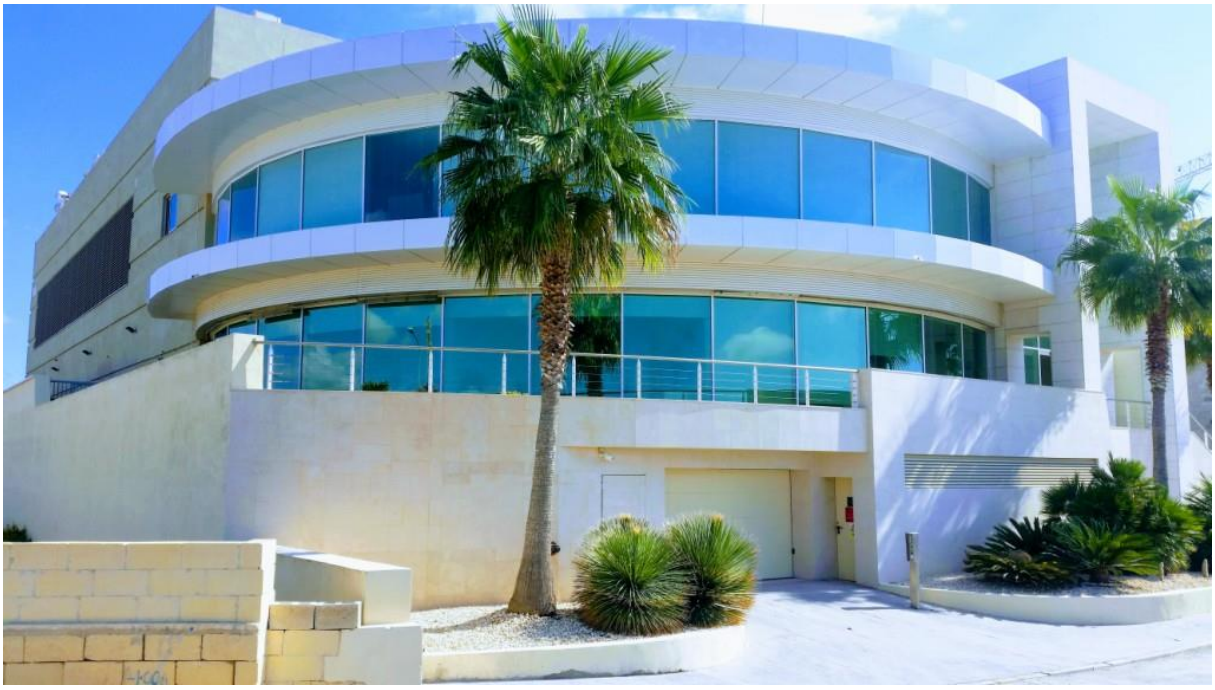
STERLING CHEMICAL MALTA LTD, HAL FAR

APPLICATION FOR VARIATION AND RENEWAL OF IPPC PERMIT

VOLUME 3: ADDENDUM 4 TO LAND AND GROUNDWATER RISK ASSESSMENT



Version 2: April 2024

Report Reference:

En-Sure Ltd, 2024. Sterling Chemical Malta Ltd, Hal Far. Application for Variation of IPPC Permit: Volume 3: Addendum 4 to Land and Groundwater Risk Assessment (Version: 2). San Gwann, April 2024; vi + 21 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
April 2024

Report for: Sterling Chemical Malta Ltd

Revision Schedule

Rev	Date	Details	Prepared by	Reviewed by	Approved by
00	Oct. 2022	Submission to client	**Collette Lynch** Environmental Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director
01	June 2023	Submission to ERA	**Collette Lynch** Environmental Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director
02	April 2024	Updates following ERA public consultation	**Collette Lynch** Environmental Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director

File ref: N:_Active Projects\Environmental Permitting\ES_STG013 - Sterling variation micronisation\IPPC\Submissions April 2024\Vol 3 - Land & groundwater risk assessment v5_FNL.docx

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ADDENDUM 4 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 addition of new emission points to air from the micronisation facility and a fire safety cabinet installed to store raw materials. Additionally, the discharging of RO reject from a small-scale RO unit to sewer, plus changes to the layout of the Waste Warehouse, to include the storage of raw materials.

4. From hereinunder, the Waste Warehouse will be referred to as the 22-MR Warehouse since the current variation includes permission to additionally store non-waste items in addition to the existing waste.

5. 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. Three 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.

    - 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; and

[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.

- Addendum 3[4] covered 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.

6. The current Addendum (Addendum 4) 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.

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

Figure 1: Site location

Location of site

Legend

Site boundary

Sterling IPPC Micronisation Variation

Map by:

Client: Sterling Chemical Ltd
Ref: ES_STG013
Date: 1 / 2022

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Description of the Variations

7. The proposed variations comprise the addition of new emission points to air from the micronisation facility and a fire safety cabinet installed to store raw materials, in addition to the discharging of RO reject from a small-scale RO unit to sewer, plus changes to the layout of the Waste Warehouse, to include the storage of raw materials.

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

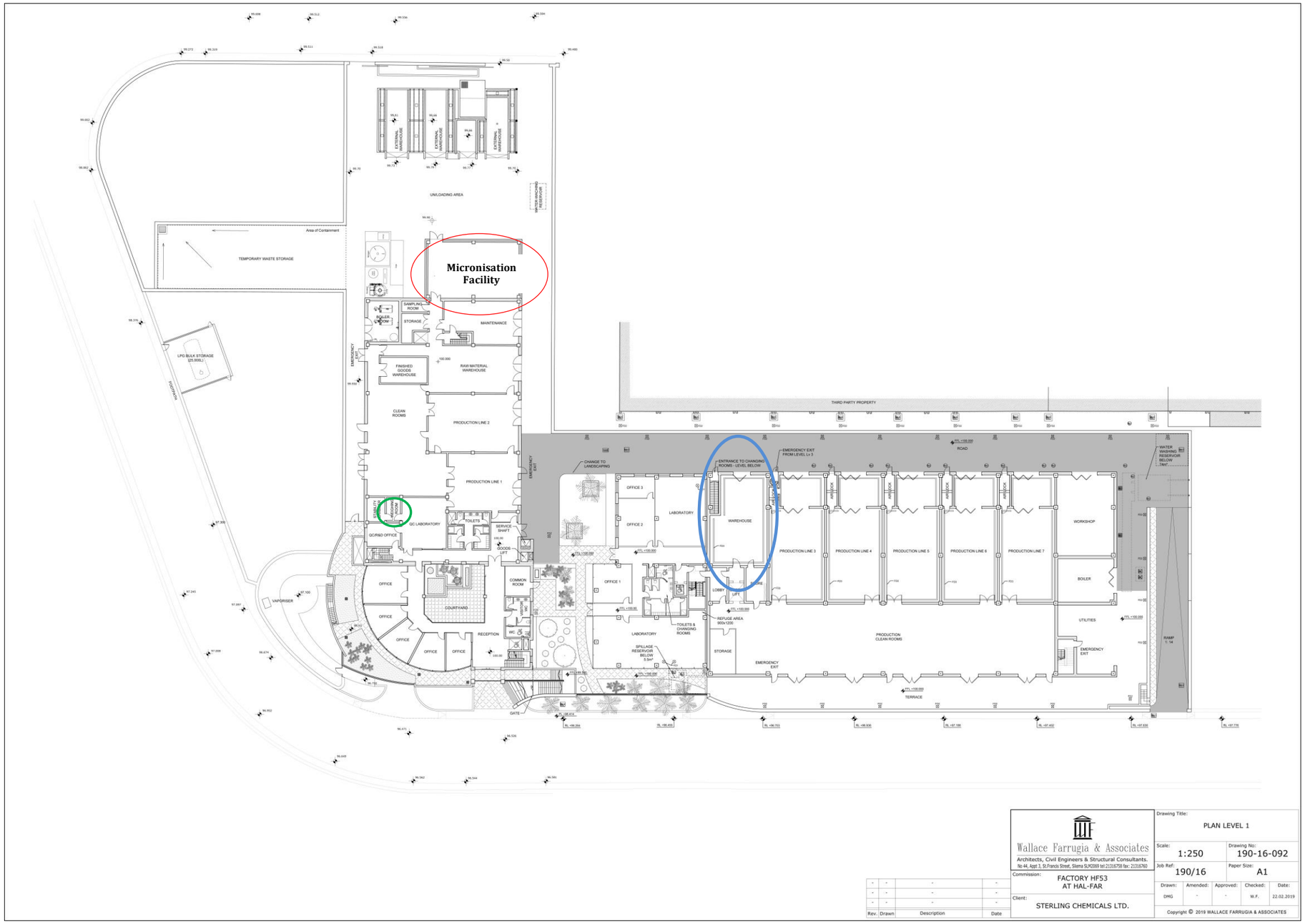
9. The following subsections summarise the aspects of these proposals that are relevant to the contamination of land and groundwater, and the associated mitigation.

10. As mentioned, the proposed variations include the addition of five new emission points to air, as shown in **Table 1**, which also summarises the abatement applicable to each emission point. In addition to assessing risks to land ground water from emissions to air, the storage of raw materials has also been considered; however, it is noted that very small quantities of chemicals are proposed to be stored in the fire safety cabinet (corresponding to emission point EM23).

Table 1: New emission points to air

Ref.	Source	Abatement
EM23	Microniser	HEPA Filter
EM24	Ventilation system of fire safety cabinet	HEPA filter and extraction vent

Figure 2: Layout of the facility (Level 1)



The location of the micronisation facility is circled in red, the proposed fire safety cabinets is circled in green and the 22-MR Warehouse is circled in blue.

11. Additionally, the proposal includes the discharging of reverse osmosis (RO) reject to sewer from a small-scale RO unit in the Q.C Laboratory.

Fire Prevention and Response

12. 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.

13. The cabinet selected to store the raw materials, which will mainly consist of flammable solvents, is certified to EN14470-1: fire safety storage cabinets standard. Furthermore, the room in which the cabinet is to be stored includes a break glass manual call point, an internal fire sounder and a flashing beacon as alarm systems.

14. Addendum 3[5] of this Risk Assessment, included details on the fire prevention and response provisions for the 22-MR Warehouse (formally referred to as the Waste Warehouse). All provisions are still in place. Furthermore, it is noted that only non-flammable raw materials, namely solvents, will be stored in the 22-MR Warehouse.

Relevant Hazardous Substances and Waste

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

Table 2: Contaminants and relevance to land / groundwater contamination

Proposed variation	Contaminant types	Relevance	Justification
Storage of raw materials in fire safety cabinet	Solvents (usually flammable), reagents, APIs	Relevant	• Without mitigation, in the event of a spill emissions to of VOCs could be released to land.
Emissions from Micronisation facility (EM22)	Solvents reagents, APIs	Relevant	• Without mitigation, emissions to air may be released and eventually contaminate land. • Emissions could also dissolve in wash water during floor cleaning and may also contaminate used firefighting water.

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

Proposed variation	Contaminant types	Relevance	Justification
RO Reject discharge to sewer	Brine (Non-hazardous)	Not relevant	• RO reject is non-hazardous
Storage of raw materials in the 22-MR Warehouse	Solvents	Relevant	• Without mitigation, emissions to air may be released and eventually contaminate land. • Emissions could also dissolve in wash water during floor cleaning and may also contaminate used firefighting water.

Risk Assessment

Overview

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

17. **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.

18. **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	
			Structural mitigation measures	Operational mitigation measures
Emission to air from a spill of a raw material from inside the fire safety cabinet during storage (EM24)	Air dispersion (prevailing wind direction); wet / dry deposition[6]	• Land • Groundwater		• Extraction system • Carbon filter
Emissions to air from Micronisation facility (EM23)	Air dispersion (prevailing wind direction); wet / dry deposition[6]	• Land • Groundwater		• Cyclone filter • HEPA filters
Release of used extinguishant from the QC Laboratory where the fire safety cabinet is stored (generated in case of a fire), contaminated with raw materials, mainly solvents)	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 25 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 • Training of personnel in fire prevention and basic fire fighting • Fires safety cabinet constructed to EN14470-1 EN16121 standard, designed to withhold a fire for 90 minutes.
A spill of a raw materials, namely a non-flammable solvent from the 22-MR Warehouse	Direct contamination; permeable strata above water table4; used washwater[6]	• Land • Groundwater	• Underlying impermeable concrete layer • Gutters leading to a 57 m^3 concreted water washing reservoir.	• Spill kit • Spill SOP

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

Release of used extinguishant from the 22-MR Warehouse (generated in case of a fire), contaminated with on-flammable solvents)	Direct contamination; permeable strata above water table; used washwater	• 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 available in the 22-MR Warehouse) • Training of personnel in fire prevention and basic fire fighting. • Only non-flammable waste and raw materials are stored.

Identification of Potential Releases

919. The scenario of an accidental spill of a raw material within the QC laboratory has already been assessed in the original Land and Groundwater Risk Assessment[7], where all pollutant linkages were removed once mitigation was applied. This assessment considers the risks to land and groundwater in the event of an accidental spillage of raw material from within the fire safety cabinet, in particular, the release of volatile organic compounds (VOCs) to air. Mitigation measures will be in place to reduce air emissions, as described in **Table 3**.

20. Additionally, air emissions primarily VOCs and / or APIs are generated during the micronisation process. Once again, mitigation measures will be in place to reduce air emissions (**Table 3**).

21. Used extinguishant would also be generated in the event of a fire within the QC laboratory where the fire safety cabinets storing the raw materials will be place. The extinguishant may become contaminated with raw material.

22. Whilst both scenarios of a spillage of hazardous waste and a fire breaking out in the 22-MR Warehouse generating used extinguishant, which could be contaminated with hazardous waste, was assessed in Addendum 3 of the Land and Groundwater Risk Assessment[8], this Risk Assessment considers the scenarios of a spill of a raw material and a fire generating used extinguishant, which potentially could be contaminated with raw materials in addition to waste the 22-MR Warehouse.

Identification of Migration Pathways

23. 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. In the absence of mitigation (such as filters), emissions to air could eventually contaminate the land and in time could potentially reach the groundwater through permeable rock strata and underlying the Scheme site, or though other routes such as fissures.

25. Another pathway could potentially be the direct contamination of the permeable strata above the water table and / or rainwater runoff as a result of a fire breaking out in the QC laboratory, where the fire safety cabinet containing the raw materials is stored or the 22-MR Warehouse, where both hazardous waste and raw materials will be stored. Without mitigation (such as containment), used

[7]En-Sure Ltd, 2015. Sterling Chemical Malta Ltd, Ħal Far: Land and Groundwater Risk Assessment (Version 1). San Ġwann, December 2015; iv + 41 pp. + 3 Appendices.

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

fire extinguishant, potentially containing VOCs, would be allowed to contaminate the

26. 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

27. 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.

28. 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.

29. 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.[9]

30. 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*.

31. 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.

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

Figure 3: Geology of the site and its surroundings

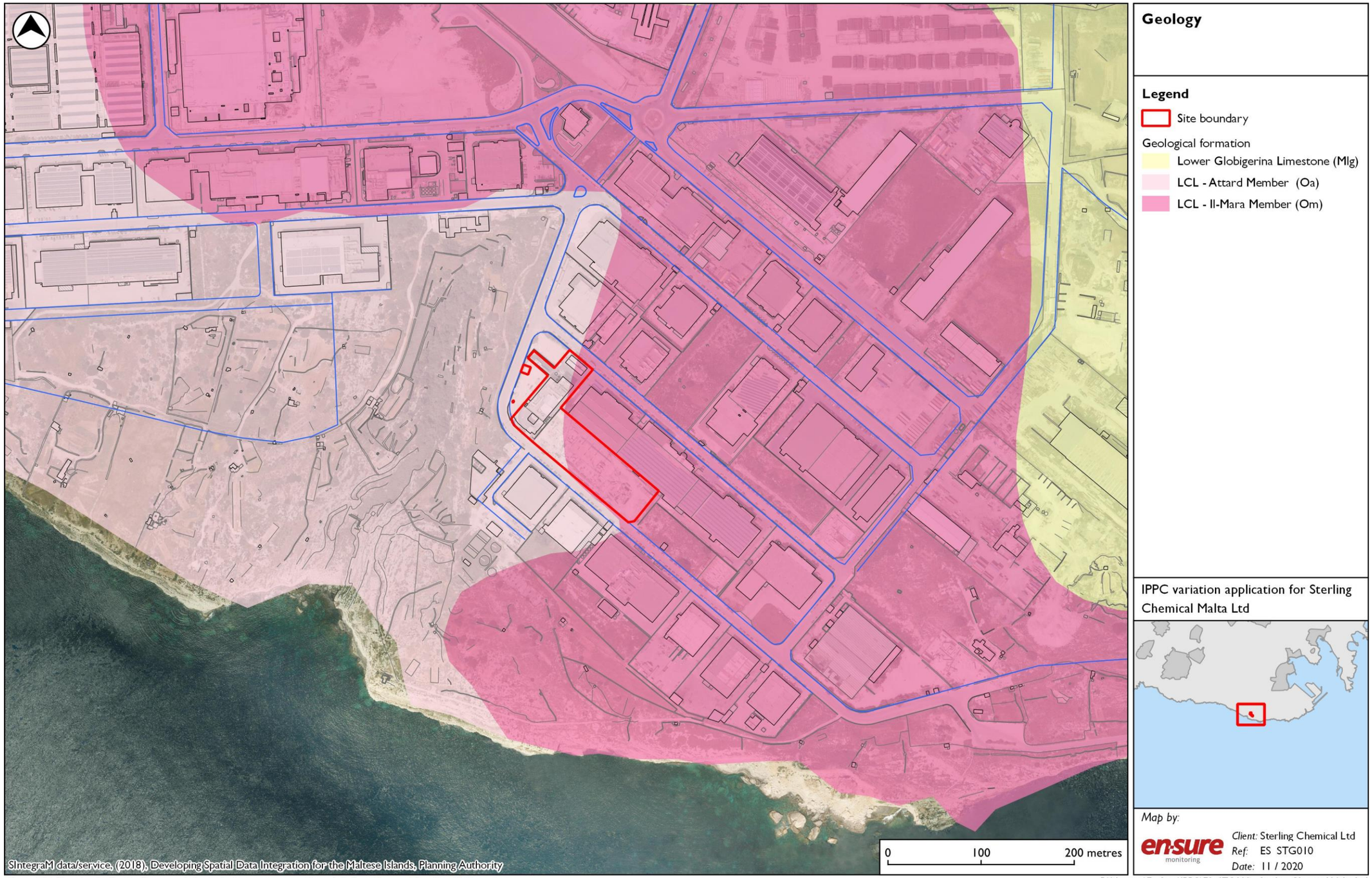


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Figure 4: Hydrology of the site and its surroundings

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Figure 5: Environmental designations

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Risk Evaluation

32. The risks to land and groundwater have been assessed using the same evaluation criteria as in all previous original risk assessments. A copy of the criteria can be seen **Appendix 1**. 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

33. **Table 4** 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
Emission to air caused by a spill of raw materials from within the fire safety cabinet (EM24)	Minor	Likely	Moderate
Emissions to air from the microniser (nitrogen output) (EM23)	Minor	Almost certain	Moderate
Release of used contaminated extinguishant from the QC laboratory.	Minor	Occasional	Moderate
A spill of a raw materials within the 22-MR Warehouse	Minor	Likely	Moderate
Release of used contaminated extinguishant from the 22-MR Warehouse.	Moderate	Occasional	High

34. The likelihood of an accidental spill of a raw material in the fire safety cabinet stored in the QC laboratory is classified as 'likely' without precautions. However, such spills are likely to be very small (up to 125 L if the largest raw material stored was to spill), and therefore have minor environmental consequences.

35. In the scenario without mitigation, emissions to air would be routinely generated during the micronisation process from emission point EM23; although, only when jet milling at high pressure is required since the nitrogen cannot be reused but instead is required to be released. Therefore, given that the quantity of potential pollutants released is low, the consequent environmental effects have been classified as minor.

36. It is considered that runoff of used extinguishant from the QC laboratory would result in minor environmental consequences if the used extinguishant is contaminated with raw materials stored in the fire safety cabinet, since minimal amounts of raw materials to be stored. Without mitigation, taking into account the flammability of the substances to be stored, it is considered that a fire may occur occasionally.

37. A spill of a raw material from the 22-MR Warehouse would have a minor effect on the environment given the fact that typically, only one container of a raw material would be spilt at any one time. The likelihood of such a spill has been considered likely and therefore, the resultant risk has been considered as 'moderate'.

38. However, in the event that a fire was to break out in the 22-MR Warehouse, used extinguishant could be contaminated with both hazardous waste and raw materials, which may contain VOCs, thus increasing the negative effect on the environment to a 'moderate'. The likelihood of such an event has been considered 'occasional', and therefore, the resultant risk of a release of used contaminated extinguishant has been classified as 'high'.

With Mitigation

39. **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
Emissions to air caused by a spill of raw materials from within the fire safety cabinet (EM24)	Insignificant	Occasional	Very Low
Emissions to air from the microniser (nitrogen output) (EM23)	Insignificant	Almost certain	Low
Release of used contaminated extinguishant from the QC laboratory.	No pollutant linkages		None
A spill of a raw materials within the 22-MR Warehouse	No pollutant linkages		None
Release of used contaminated extinguishant from the 22-MR Warehouse.	No pollutant linkages		None

40. Since the QC laboratory is connected to a wash water reservoir, via underground pipes that are periodically certified for impermeability, the pollutant linkage related to the release of used extinguishant is completely removed.

41. When applying mitigation to the emission to air point from the fire safety cabinet (**EM24**), the environmental consequence has been reduced to 'insignificant', which reduced the resultant risk level from moderate to very low. Likewise, there is a reduction in the resulting risk level when considering the scenario of installing mitigation to the additional emission to air point from the microniser (**EM23**), where the risk has reduced from moderate to low. Therefore, additional emissions to air as a result of the proposal are not expected to have a significant impact on the environment, due to the abatement systems that will be in place.

42. When applying mitigation measures against a spill of a raw materials in the 22-MR Warehouse, all pollutant linkages have been removed, since any residues remaining once the spill has been cleaned up as per procedure, will be diverted via underground pipes, that are certified for their impermeability, to a concrete reservoir – the contents of which is exported for further treatment.

43. Likewise, when considering the resultant risk level once the measures to mitigate against the impact of a release of contaminated extinguishant from the 22-MR Warehouse have been applied, all pollutant linkages have been removed. Fire prevention and response systems already in place reduce the likelihood and severity of a fire; however, if a fire does break out, used extinguishant will be directed to a 57 m^3 reservoir and exported for further treatment.

Conclusion and Recommendations

44. 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 very low, low and on three accounts, all pollutant linkages were removed.

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

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

47. 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

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

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	