

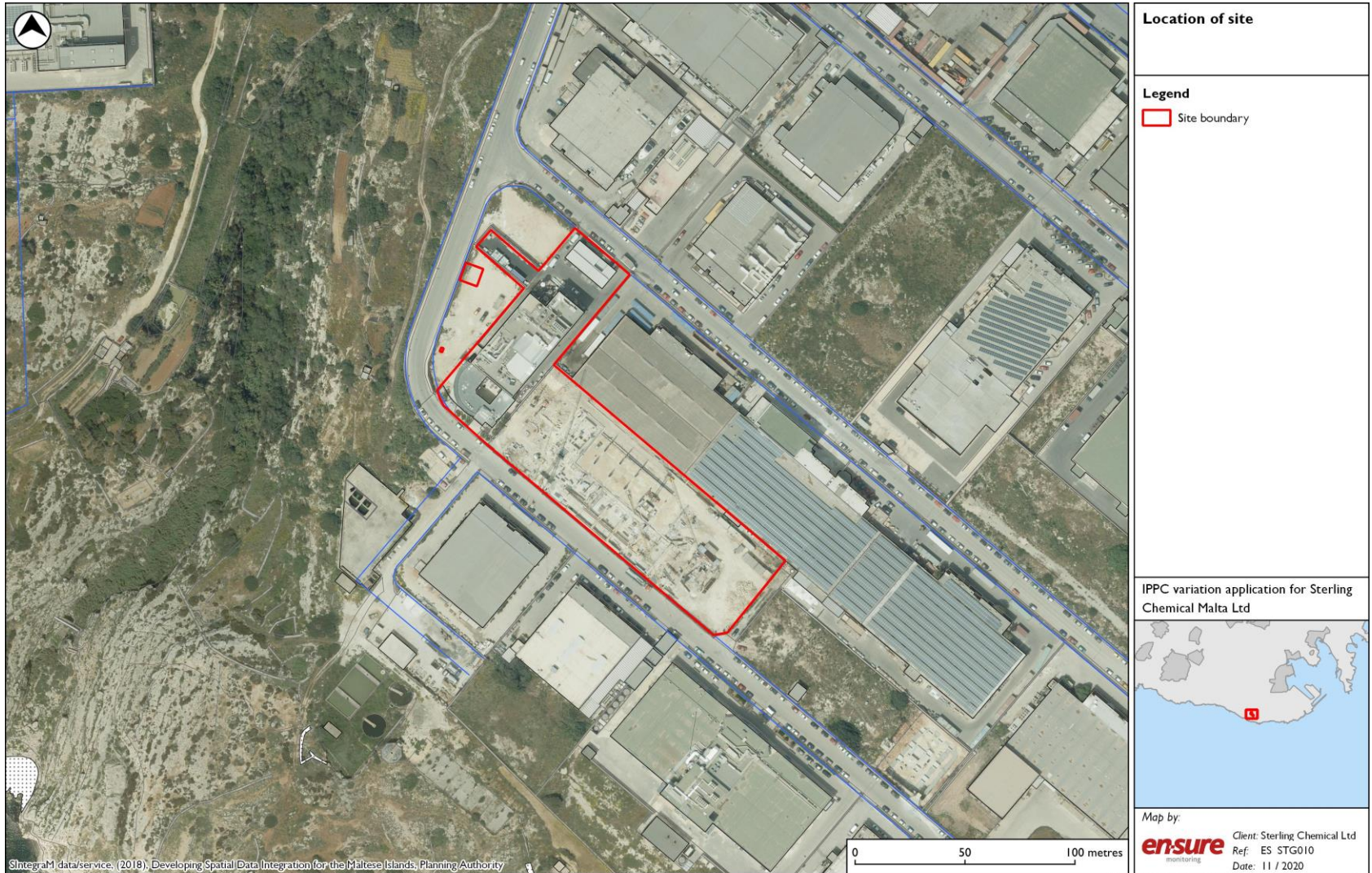
***en-sure***  
monitoring



# **Sterling Chemical Malta Ltd**

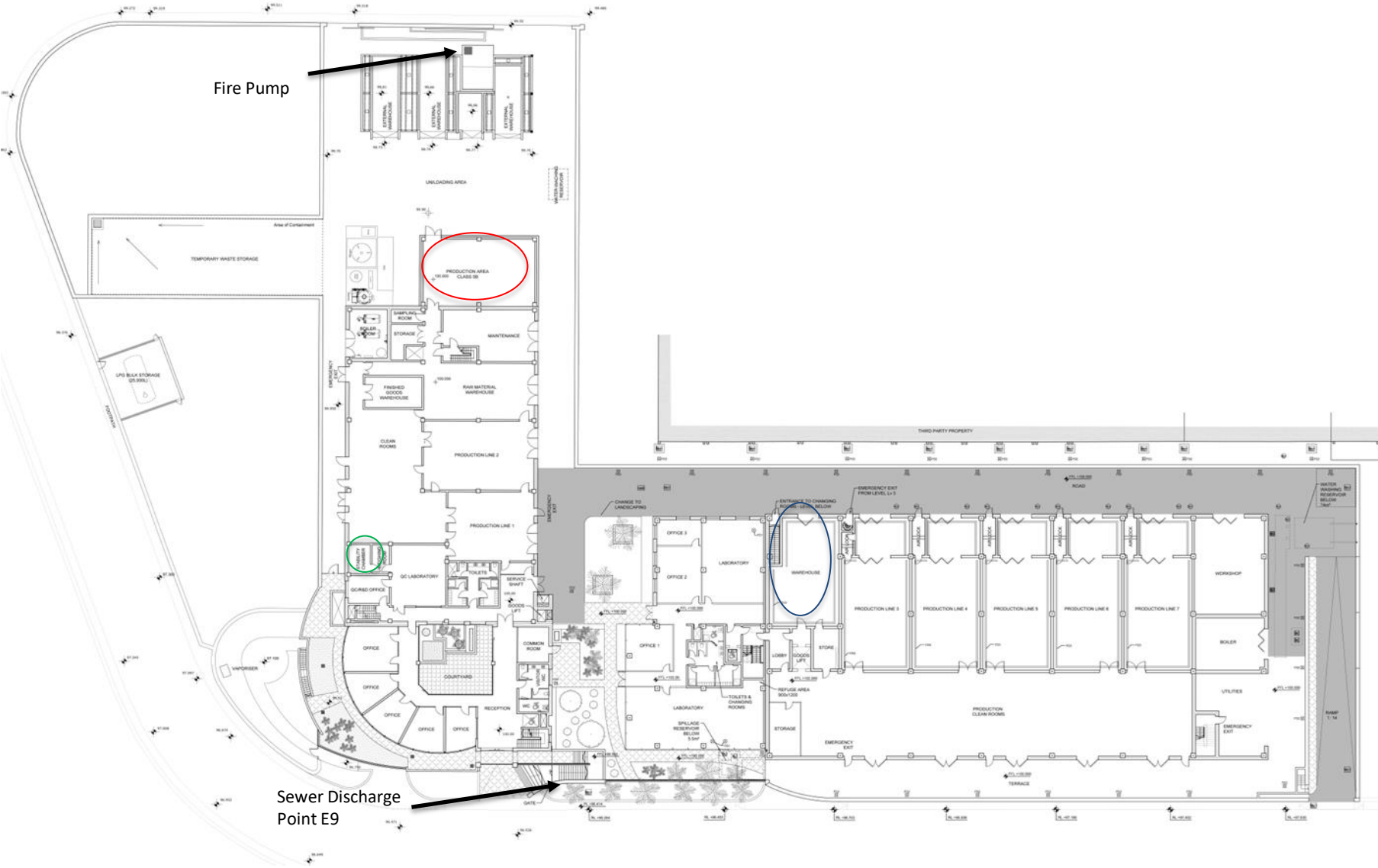
**Application for renewal and variation of IPPC  
permit**

IP 0001/23



- The introduction of three additional emission to air points:
  - Nitrogen outlet of the micronisation plant
  - Ventilation system output for four fire safety cabinets for the storage of raw materials, proposal also included the relocation of a small amount of raw materials to the cabinets
  - The inclusion of the existing emission to air point emanating from the diesel operated emergency fire pump
- The inclusion of reverse osmosis (RO) reject water as a source of effluent being discharged to sewer
- Changes to the use and layout of the Waste Warehouse (22-MR), to include the storage of raw materials
- Amendments to the Emissions to Air Monitoring Programme

# Scheme Layout



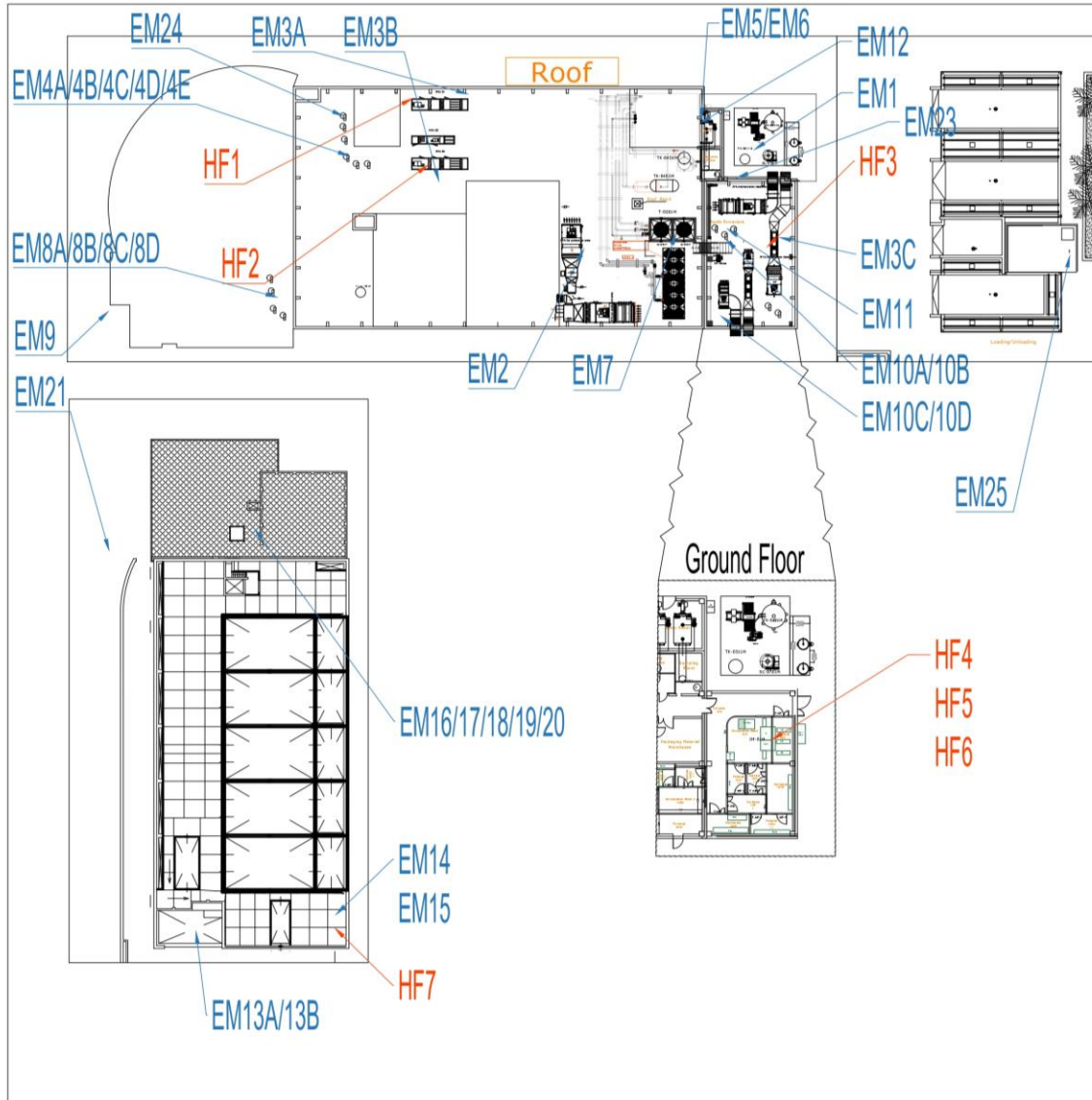
- The Microniser is an existing authorised piece of equipment which uses a process of jet milling to reduce the particle size of the final pharmaceutical products
- In order to increase the jet milling pressure, the nitrogen, which is used as the inerting gas, needs to be released so not to overload the system
- The waste gas will be processed through existing HEPA filters and will leave the facility via Emission Point **EM23**
- Emission Point **EM23** will be subject to annual monitoring

- For logistic reasons, a small amount of flammable raw materials (mainly solvents) are to be stored in the Q.C laboratory in four fire safety cabinets.
- The cabinets require their own ventilation system in order to control the temperature.
- An additional emission to air point - **EM24** is therefore required.

- One of the four existing emergency fire pumps is diesel-operated
- In the rare event it is activated, there would be an emission of combustion by-products to air
- The source of this emission is being included as Emission Point **EM25** in the application



## Emission Point Layout Plan



Malta1	Column1	Malta2	Column2
Emission Point Ref.	Source	Emission Point Ref.	Source
EM1	Scrubber	EM13A/13B	Scrubber
EM2	HVAC P1 (general ventilation)	EM14	HVAC P4 (general ventilation)
EM3A	HVAC Line 2 (HEPA)	EM15	HVAC Line 7 (HEPA)
EM3B	HVAC Line 1 (HEPA)	EM22	22 MR Ventilation Warehouse
EM3C	UTA-JM002M		
EM23	Micronizer Nitrogen Exhaust		
EM4A/4D	QC1 Lab Fume Hoods	EM16/17/18/19/20	Future Fume Hoods
EM4B	QC1/QC2 Lab Cabinet		
EM4C/4E	QC2 Lab Fume Hoods		
EM24	QC1 Lab Reagent Fire Cabinet		
EM5	Boiler 1		
EM6	Boiler 2		
EM7	Cooling Tower		
EM8A/8B/8C	AMS Lab Fume Hoods		
EM8D	AMS Lab Cabinet and Localized Hoods	EM21	Sewage
EM9	Sewage		
EM10A/10B/10C/10D	R&D Lab Fume Hoods		
EM11	R&D Sink Hood		
EM12	Cold room		
EM23	Nitrogen Micronizer Exhaust		
EM25	Emergency Fire Diesel Pump		

Sterling ID	ERA Filter Item	Location	Type
AHU1	HF1	Roof Malta1	Supply and Exhaust Air Handling Unit for Production Line 2
AHU3	HF2	Roof Malta1	Supply and Exhaust Air Handling Unit for Production Line 1
UTA-JM002M	HF3	Roof Micro	Supply and Exhaust Air Handling Unit for Micronization
CH01	HF4	Micro Clean Room	Extraction System Micronizer
CH02	HF5	Micro Clean Room	Extraction System Micronizer
CH03	HF6	Micro Clean Room	Extraction System Micronizer
UTA-HVAC-0702M	HF7	Roof Malta2	Supply and Exhaust Air Handling Unit for Production Line 7

14	03/05/2024	New Emission points Micronizer, Diesel Pump	AN		
13	09/08/2022	Lab Reagent Cabinets	AN		
12	05/10/2021	Steam Boiler Malta1 Design	AN		
11	23/07/2020	Substitution Chiller +5, Overflow tank placement	AN		
10	13/10/2020	Emission as per IPPC permit. New carbon filters	AN		
9	17/12/2019	LPG tanks removal	AN		
8	16/07/2019	HEPA Malta2, Sampling Room, SAS 1P, AMS	AN		
7	30/01/2019	HEPA Filters for ERA	AN		
6	21/08/2018	DU-01M Distillation Unit, VP-8021M, C-0502M and TK-1001M	MCM		
5	23/06/2017	New Reactor in line 1, Micro building	AN		
4	15/11/2016	Cold Rooms Installation, new reactors in line 2, pilot reactors relocation	RV		
3	04/06/2015	Flammable Warehouse extension - As built	RV		
2	23/02/2015	Installation of Line 1 - As built	RV		
1	08/10/2014	Revision for new equipments	RV		
0	18/06/2014	First Emission	RV		
REV	DATE	DESCRIPTION	DESIGNER	CHK	APPR.
REV	DATE	DESCRIPTION	DWG. DWL	CONTR. CHK	APPR.
Sterling Chemical Malta Ltd HF51 - Hal Far Industrial Estate Birzebbuga - BBG3000 MALTA			DIS. N. DWG. N. Scale 1 1/1	DGH_03_2014 1/1	
OGGETTO - OBJECT Equipments Layout - Emission and HEPA Filters			DATE 19/06/2014	DESIGNATOR COMPILE RV	
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- The RO reject from a small-scale RO system is currently channeled to IBC tanks and sent abroad for further treatment.
- This application includes the discharging of such effluent to existing sewer connection **E9**.
- Permission from WSC has already been obtained.



- Currently the 22-MR Warehouse (formally referred to as the Waste Warehouse) only stores non-flammable and non-hazardous waste.
- For logistical reason, the proposal includes the additional storage of raw materials (mainly solvents).
- No new raw materials are being proposed. Materials will be stored in appropriate containers – i.e. IBCs, drums, all of which will be placed on pallets.
- The 22-MR is connected to the ‘wash water reservoir’ via stainless steel gutters.

- No new additional waste streams are expected to be generated as a result of the proposals.
- There are only slight increases in the amount of the following waste streams.

<b>EWC code</b>	<b>Description</b>
15 02 02*	Filters contaminated with hazardous substances
15 01 10*	Contaminated packaging

- No potential releases to land or groundwater have been identified.
- In the event of a spillage of raw materials within the fire safety cabinet, all liquids will be collected in the integrated bund.
- Residue spillages occurring outside of the cabinet will be channelled, towards the wastewater reservoir and managed appropriately.
- The 22-MR Warehouse is also connected to the wastewater reservoir.

New source of emissions to air include:

<b>Emission Point</b>	<b>Source</b>	<b>Parameter</b>	<b>Abatement</b>	<b>Monitoring</b>
EM23	Nitrogen Outlet (Microniser)	PM	HEPA Filters	Annual
EM24	Fire Safety Cabinets	VOCs (*)	Carbon Filter	None
EM25	Fire Pump	Combustion by-products (**)	None	None

(\*) A release will only occur in the event of a spill of a raw material

(\*\*) A release will only occur in the event that the fire pump is activated

Following the following BAT assessment: **Common Waste Gas Management and Treatment Systems in the Chemical Sector**, the additional highlighted waste gasses have now been added to the **Emissions to Air Monitoring Programme**

Emission Limits to Air and Monitoring			
Emission Point Reference	Parameter	Limit	Frequency
EM1 EM13A-B	Total VOC	20 mg C/Nm <sup>3</sup>	Annually
	CO (Carbon Monoxide)	N/A	
	HCl (Gaseous Chloride)	7.5 mg/Nm <sup>3</sup>	
	HF (Gaseous Fluoride)	<1 mg/Nm <sup>3</sup>	
	Total Particulate Matter (Dust)	<1 mg/Nm <sup>3</sup>	Every 6 months
	NH3 (Ammonia)	10 mg/Nm <sup>3</sup>	
	SO2 (Sulphur Dioxide)	<150 mg/Nm <sup>3</sup>	
	Toluene	<1 mg/Nm <sup>3</sup>	
	Dichloromethane	<1 mg/Nm <sup>3</sup>	
	Dimethylformamide	2 mg/Nm <sup>3</sup>	
	Tetrahydrofuran	10 mg/Nm <sup>3</sup>	
	Methyl Isobutyl	10 mg/Nm <sup>3</sup>	
EM3A-C EM15	Total Particulate Matter (Dust)	<1 mg/Nm <sup>3</sup>	Annually
EM4A-E EM8A-D EM10A-D EM11	Total VOC	20 mg C/Nm <sup>3</sup>	Every 4 years <sup>i</sup>
	Total Particulate Matter (Dust)	<1 mg/Nm <sup>3</sup>	
EM23	Total Particulate Matter (Dust)	<1 mg/Nm <sup>3</sup>	

- Emissions to air mitigated and monitored as required
- Risk to land and groundwater, with mitigation, is none (no pollutant linkage) to low



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