

Annex C-4: Emissions and Monitoring

	4000 Litre Reaction Vessel	kilo-Lab	Pre-fabricated Mobile Lab
1. Waste Streams	No change, same waste streams as per current permit. Quantities merge with those of the rest of the plant (as declared in Annual Environmental Report and E-PRTR Report).	No change, same waste streams as per current permit. Quantities merge with those of the rest of the plant (as declared in Annual Environmental Report and E-PRTR Report).	Small amounts of wastes with EWC codes 07 07 04, 07 07 10, 18 01 08 and 16 05 06 will be produced. The amounts generated are estimated to be less than 1% of waste generated in the current manufacturing plant.
2. Waste Management	No change from what is specified in the current permit. Handled together with the wastes generated by the production plant.	No change from what is specified in the current permit. Handled together with the wastes generated by the production plant.	Since the generation of waste is estimated to be low, no specific or special storage site for this waste will be needed. It will be handled together with the wastes generated by the other laboratories located on the premises.
3. Disposal/recovery	Solid waste is currently sent to the WasteServ Marsa Treatment facility for incineration, or exported as may be the case. Liquid waste is exported.	Solid waste is currently sent to the WasteServ Marsa Treatment facility for incineration, or exported as may be the case. Liquid waste is exported.	Recovery of this waste will not be an option due to the small volumes involved. Wastes will be handled by our waste brokers to be exported to authorised waste treatment facilities.
4. Emissions to air	Since the processes carried out in the 4000 litre reaction vessel are no different than those previously carried out in the plant, abatement is also as specified in the current IPPC permit.	The processes in the kilo-Lab are similar to the ones in the R&D laboratory and are performed within a fumehood of similar design to that of the other laboratories.	Although a new emission point is being declared (another HVAC outlet), no emissions to air are being envisaged. This is mainly due to complete containment technology, within a double closed system. The HEPA filters that are incorporated into the installation are designed to be the 3 rd barrier to avoid any possible emission to the atmosphere, even in the remote case that the first and second barriers fail.

5. Emissions to sewer	<p>Since the processes carried out in the 4000 litre reaction vessel are no different than those previously carried out in the plant, no different contaminants will be expected to be present in the aqueous waste. Waste streams are characterised and are only directed to the waste water treatment plant if they do not jeopardise the current Sewer Discharge Permit.</p>	<p>The processes in the kilo-Lab are similar to the ones in the R&D laboratory and small volumes of waste are produced. Aqueous wastes are treated in the same way as the aqueous wastes generated by the manufacturing plant.</p>	<p>Effluents arising from the rinsing of equipment which is contaminated with APIs will not be directed to the waste water treatment plant but collected in separate receptacles and sent for treatment at appropriate waste treatment facilities. On the other hand, water used for the washing of floors and other non-contaminated areas will be directed to the waste water treatment plant.</p>
6. Monitoring	No new emission points.	No new emission points.	<p>New emission point (another HVAC outlet), to be handled as the other HVAC outlets, currently permitted. Amend Table 2.2.2, emission point 4, location of emission point to read "points 4a and 4b on Site Drawing No. 4" (drawing to be amended as in Annex C-6).</p>
7. Environmental Statements	None required.	None required.	<p>Environmental Statement dated 30 October, 2012 (tracking number 148783) by Dr. Paul Gauci, as per MEPA's request.</p>