



Manufacture of Organic Fine Chemicals BREF - Assessment Report

Novartis Ringaskiddy Limited HSE Projects IE0311525-22-RP-0007, Issue: A

Issue date: 22 Jul 2020



Document Sign Off

Manufacture of Organic Fine Chemicals BREF - Assessment Report

Novartis Ringaskiddy Limited HSE Projects IE0311525-22-RP-0007, Issue A

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CURRENT IS	CURRENT ISSUE					
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PREVI	PREVIOUS ISSUES						
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162.TP.009, Issue 7, 16/01/2013 Formal Issue



Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals (extracts)

The full and complete Manufacture Organic Fine Chemicals BAT reference document (Feb 2009) is available at the EIPPC Bureau website: http://eippcb.jrc.ec.europa.eu/reference/

BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	5.1.1	BAT for Prevention of environmental impact		
1	5.1.1.1	BAT is to provide an auditable trail for the integration of environmental, health and safety considerations into process development (see Section 4.1.2).	Applicable. All changes at Novartis Ringaskiddy Ltd. (NRL) are managed through SOP-8000454 'Change Control SOP' and procedure SOP 8008145 'Health Safety and Environmental Change Control' ensures the management of changes, which could impact Health, Safety and Environmental (HSE) considerations. For all changes with HSE impact a hazard evaluation is required, with the level of assessment dependent upon the scale of the change and the risk involved. The procedure prompts the update of critical documents such as P&IDs, raw material specifications, operating procedures, emergency procedures, maintenance and inspection requirements and Hazard Area Classifications. Process development within Novartis, involves the following three steps/stages:	BAT In Place

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			 R&D Division of Novartis develops the initial process The Chemical & Analytical Development (for Chemical operations) Section of Novartis investigates how best to manufacture the process at large scale (up to Pilot Plant scale) Final Manufacture (which is the step relevant to Novartis Ringaskiddy Ltd (NRL)). The initial large scale manufacturing step involves the production of three validation batches Stages 2 to 3 involve rigorous recording of results/tests and assessments including HSE assessments. HSE assessments use the Process Hazard Analysis (PHA) tool Zurich Hazard Analysis, which take place prior to the transfer of new processes from the Chemical & Analytical Development section to NRL for manufacturing. 	
2	5.1.1.1	BAT is to develop new processes as follows (see Section 4.1.1): a) to improve process design to maximise the incorporation of all the input materials used into the final product (see, e.g. Sections 4.1.4.3 and 4.1.4.8)	Applicable. Green Chemistry considerations are taking into account during the Chemical & Analytical Development stage of new processes. Also at this stage a solvent selection guide is used. NRL has involvement in the Green Chemistry assessment during new product introduction to the site. Optimisation of manufacturing processes also occurs at NRL.	BAT In Place

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		b) to use substances that possess little or no toxicity to human health and the environment. Substances should be chosen in order to minimise the potential for accidents, releases, explosions and fires (e.g. for solvent selection, see Section 4.1.3).		
		c) to avoid the use of auxillary substances (e.g. solvents, separation agents, etc. see e.g. Section 4.1.4.2)		
		d) to minimise energy requirements in recognition of the associated environmental and economic impacts. Reactions at ambient temperatures and pressures should be preferred		
		e) to use renewable feedstock rather than depleting, wherever technically and economically practicable		
		f) to avoid unnecessary derivation (e.g. blocking or protection groups)		
		g) to apply catalytic reagents, which are typically superior to stoichiometric reagents (see, e.g. Sections 4.1.4.4 and 4.1.4.5)		

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3	5.1.1.2.1	BAT is to carry out a structured safety assessment for normal operation and to take into account effects due to deviations of the chemical process and deviations in the operation of the plant (see Section 4.1.6).	Applicable. Various tools are used on site for process safety risk assessment, where deviations from normal operation are assessed. Site procedure OPS-SARE-00213611 'Guide for Risk Assessment at NRL' provides guidance as to the appropriate selection of risk assessments. The type of risk assessments performed include the following: - Zurich Hazard Analysis (ZHA): This is required for all new processes. It can also be used for assessing changes in operating parameters such a process parameter, process equipment and operating procedures. This is applied when proposed changes are outside of the description and base data used for the original process risk analysis; if the risk analysis exceeds 5 years or if there is any doubt that the original risk assessment has not covered the proposed changes. The assessment is covered by site procedure SOP-8000847 'Process Risk Analysis using Zurich Hazard Analysis (ZHA)' - Hazard and Operability Study (HAZOP): This assessment is required for modification of existing equipment or tie in of new equipment. This risk assessment follows site procedure SOP Doc OPS-	BAT In Place

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			 SARE-00222850 'Guidelines for Effective Hazard and Operability HAZOP study at Novartis Ringaskiddy Ltd.' Work Place Risk Assessments are carried out on all processes For new task or unit operations, the potential hazards including manual handling issues are assessed using FRM-8008002 'Job Hazard Analysis Form' 	
4	5.1.1.2.1	In order to ensure that a process can be controlled adequately, BAT is to apply one or a combination of the following techniques (without ranking, see Section 4.1.6.1): a) organisational measures b) concepts involving control engineering techniques c) reaction stoppers (e.g. neutralisation, quenching) d) emergency cooling e) pressure resistant construction f) pressure relief.	 Applicable. The requirement for some or all of these measures is determined during the Process Hazard Analysis Risk assessment of each process e.g. HAZOP All vessels have pressure relief devices Reactors have emergency cooling There is implementation phase following every PHA assessment and a check is performed prior to start-up that any actions arising from the review are in place. Any open actions recorded and tracked on HSE.NET (internal NRL software system) to closure. 	BAT In Place

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5	5.1.1.2.2	BAT is to establish and implement procedures and technical measures to limit risks from the handling and storage of hazardous substances (for an example, see Section 4.2.30).	 Applicable. All external storage tanks are bunded either locally or remotely. Remote bunding is provided by Spill Basins 1 and 2. The integrity and water tightness of all bunding structures and their resistance to penetration by the storage material is tested every three years in accordance with IE Licence condition 3.6.5 High Level Indication (switches) is in place on all bulk storage vessels (with feedback to the Distributed Control System) Tanker unloading procedures are in place that include how tanker overfilling is avoided (FRM-8007074 -Tank Filling Check List; SOP-8000165 - Incinerator Operations; FRM-8009367 -Tanker Filling Form; SOP-8000187- Tank Farm Operations; Method statement risk assessment for diesel deliveries). NRL is an upper tier Seveso III site. As such, the site is required to have a Major Accident Prevention Policy (MAPP) and to ensure that it is properly implemented. The MAPP is to be implemented by appropriate structures, means and by a safety management system in accordance with Annex III of 	BAT In Place

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			the Seveso III Directive. The site's Safety Report details in Section 3, the safety management system in place and the MAPP	
6	5.1.1.2.2	BAT is to provide sufficient and adequate training for operators who handle hazardous substances (for an example, see Section 4.2.29).	 Applicable. A site wide Health Safety and Environmental (HSE) training programme is in place. All employees receive HSE Site Induction training along with HSE Refresher Training. Competencies are defined in employee's respective job descriptions. All roles have specific curricula on the company's Up4Growth training and development platform to ensure that competency is being maintained. Specific process training includes process hazards and module specific training includes equipment and unit operation hazards. There is also work instruction training on tasks, including respiratory protective equipment (RPE) and personal protective equipment (PPE) training. 	BAT In Place
	5.1.2	BAT for Minimisation of environmental impact		
7	5.1.2.1	'Plant Design' BAT is to design new plants in such a way that emissions are minimised by applying techniques including the following	Applicable. - All process equipment are sealed and pressure tested prior to use (leak), with venting to the site's waste gas collection header system and onwards for treatment in	BAT In Place

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		(see Sections 4.2.1, 4.2.3, 4.2.14, 4.2.15, 4.2.21): a) using closed and sealed equipment b) closing the production building and ventilating it mechanically c) using inert gas blanketing for process equipment where VOCs are handled d) connecting reactors to one or more condensers for solvent recovery e) connecting condensers to the recovery/abatement system f) using gravity flow instead of pumps (pumps can be an important source of fugitive emissions) g) enabling the segregation and selective treatment of waste water streams h) enabling a high degree of automation by application of a modern process control system in order to ensure a stable and efficient operation.	the Liquid Vapour Incinerator (LVI) All process buildings are mechanically sealed All reactors, buffer vessels and storage vessels are nitrogen blanketed Reactors have overhead condensers. Process building floor drains and process aqueous waste drains by gravity to a lift station that is located at the WWTP New processes are assessed (as part of HSE assessment in change control) to ensure that any aqueous waste proposed to be sent to the WWTP will not negatively impact its operation. Only lightly contaminated wastewater is allowed for wastewater treatment and offsite thermal treatment is used for aqueous wastewater streams that contain non-biodegradable or toxic components. A decision flow chart is used onsite to assess which waste waters can be sent to the WWTP. Sanitary wastewater enters the biological section of WWTP directly. It does not pass through the process aqueous waste lift station; nor the Equalisation Tank and Neutralisation Basin. The sanitary wastewater is macerated prior to being pumped into the Aeration (biological treatment) Basin(s)	

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			 Processes are controlled by the site's Distributed Control System 	
8	5.1.2.2	'Groundwater protection and Water Retention Options (see BREF Sections 2.3.9 & 4.2.27)' BAT is to design, build, operate and maintain facilities, where substances (usually liquids) which represent a potential risk of contamination of ground and groundwater are handled, in such a way that spill potential is minimised. Facilities have to be sealed, stable and sufficiently resistant against possible mechanical, thermal or chemical stress (see Section 4.2.27).	 Applicable. The primary bunds on site are operated on the basis of catchment areas and directed to a remote storage bund in either Spill Basin 1 or Spill Basin 2 Spill Basins 1 and 2 are fitted with high level alarms. Sumps in the Catchment Basins that feed the spill basins are fitted with Lower Explosive Limit (LEL) detection. Sumps on the process aqueous wastewater network are fitted with high and low level alarms. All high and low level alarms feed back to the Distributed Control System (DCS) Site storage tanks and pipelines are on planned routine inspection programme (Risk Based Inspection programme) in accordance with IE Licence Requirements. A preventive maintenance (PM) system is in place through which routine maintenance checks are carried out and results recorded e.g. relevant pipelines are visually inspected weekly for leaks The storm water drains flow into the storm water retention/fire water retention pond, which consists of 	BAT In Place

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			two compartments, and out to Cork County Council storm water sewer. Water flowing into the retention ponds is monitored continuously for pH and TOC. There are two types of alarms in relation to elevated pH and TOC readings: (1) Alert alarms providing internal information to NRL regarding elevated values; (2) Action alarms in which case the storm water is retained and the EPA notified.	
9	5.1.2.2	BAT is to enable leakages to be quickly and reliably recognised (see Section 4.2.27).	Applicable. Site storage tanks and pipelines are on planned routine inspection programme (Risk Based Inspection programme) in accordance with IE Licence Requirements. A preventive maintenance (PM) system is in place through which routine maintenance checks are carried out and results recorded for e.g. pipelines are visually inspected weekly for leaks.	BAT In Place
10	5.1.2.2	BAT is to provide sufficient retention volumes to safely retain spills and leaking substances in order to enable treatment or disposal (see Section 4.2.27).	 Applicable. The primary bunds on site are operated on the basis of catchment areas and directed to a remote storage bund in either Spill Basin 1 or Spill Basin 2 The storm water drains flow into the storm water retention/fire water retention pond, which consists of 	BAT In Place

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			two compartments, and out to Cork County Council storm water sewer. Water flowing into the retention ponds is monitored continuously for pH and TOC. There are two types of alarms in relation to elevated pH and TOC readings: (1) Alert alarms providing internal information to NRL regarding elevated values; (2) Action alarms in which case the storm water is retained for further testing and/or subsequent treatment (if necessary) and the EPA notified.	
11	5.1.2.2	BAT is to provide sufficient retention volume to safely retain fire fighting water and contaminated surface water (see Section 4.2.28).	Applicable. The site has two surface water and fire water retention ponds. A 2009 Arup report "Surface Water Drainage & Fire Water Retention Pond Assessment", indicated that a total pond retention volume of 9000 m³ was needed to provide sufficient retention volume for both surface water and fire water containment. An update of this report in 2010 confirmed that following civil works on the ponds, the total retention volume was increased to 9975 m³. A risk assessment on the new EPA Guidance on fire water retention issued in 2019 is to be performed by the site for the end of July 2020.	Will Be – end of July 2020

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12	5.1.2.2	BAT is to apply all the following techniques (see also Section 4.2.27): a) carrying out loading and unloading only in designated areas protected against leakage run-off b) storing and collecting materials awaiting disposal in designated areas protected against leakage run-off c) fitting all pump sumps or other treatment plant chambers from which spillage might occur with high liquid level alarms or regularly supervising pump sumps by personnel instead d) establishing programmes for testing and inspecting tanks and pipelines including flanges and valves e) providing spill control equipment, such as containment booms and suitable absorbent material f) testing and demonstrating the integrity of bunds g) equipping tanks with overfill prevention.	 Applicable. There are two remote bunds on site, Spill Basin 1 and Spill Basin 2. Spill Basin 1 serves open catchment basins 1-5 in the Tank Farm; the truck unloading area in the Tank farm; the Solvent Recovery and Liquid Vapour Incinerator areas; the bulk liquid storage trailer park; Warehouse Number 6; and any pumped discharge from Spill Basin 2. Spill Basin 2, serves the open catchment basins 6- 10 in the Tank Farm Spill Basins 1 and 2 are fitted with high level alarms Sumps in the Catchment Basins that feed Spill Basins 1 and 2 are fitted with LEL detection. Sumps on the process aqueous wastewater network are fitted with high and low level alarms. All high and low level alarms feed back to the Distributed Control System (DCS) Site storage tanks and pipelines are on planned routine inspection programme (Risk Based Inspection programme) in accordance with IE Licence Requirements. A preventive maintenance (PM) system is in place through which routine maintenance checks are carried out and results recorded Spill kits are available as required and located at various locations onsite. They are serviced on a regular basis by a 	BAT In Place

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			third-party company; and are kept tagged to ensure that the contents are only accessed if needed - All bulk storage vessels are fitted with high and low level alarms that feed back to the DCS and a secondary instrument for high-high level	
13	5.1.2.3.1	BAT is to contain and enclose sources and to close any openings in order to minimise uncontrolled emissions (see Section 4.2.14).	 Applicable. Process emission sources are enclosed and vented to the Liquid Vapour Incinerator (LVI) for thermal treatment before being discharged to the atmosphere All of the WWTP vessels are enclosed with the exception of the two Clarifiers. Off-gases from the Process Lift Station; Equalisation Tank; Neutralisation Basin; Aeration Basins; and Aerobic Digester are vented for thermal treatment to the site's LVI 	BAT In Place
14	5.1.2.3.2	BAT is to carry out drying by using closed circuits, including condensers for solvent recovery (see Section 4.2.14)	Applicable. Approximately 95% of dryers are fitted with overhead condensers. The remaining 5% of dryers are small scale and do not have condensers as either (1) the quantity of solvent is not significant e.g. 5 – 10 litres per batch or (2) condensation of solvent is not feasible e.g. in the case of dichloromethane where a cryogenic cooler is used.	BAT In Place

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15	5.1.2.3.3	BAT is to keep equipment closed for rinsing and cleaning with solvents (see Section 4.2.14).	Applicable. Process emissions sources are enclosed and vented to the site's LVI.	BAT In Place
16	5.1.2.3.4	BAT is to use recirculation of process vapours where purity requirements allow this (see Section 4.2.14)	Applicable. There is direct recovery and reuse of solvent within individual processes in the production buildings.	BAT In Place
17	5.1.2.4.1	BAT is to close any unnecessary openings in order to prevent air being sucked to the gas collection system via the process equipment (see Sections 4.2.14 and 4.3.5.17)	Applicable. All process vessels are closed, the production buildings are closed and serviced by mechanical ventilation throughout.	BAT In Place
18	5.1.2.4.2	BAT is to ensure the airtightness of process equipment, especially of vessels (see Section 4.2.16).	 Applicable. All process vessels are closed for GMP purposes and are pressure tested as part of the inertion sequence The inertion sequence tests the air tightness of the vessels 	BAT In Place
19	5.1.2.4.3	BAT is to apply shock inertisation instead of continuous inertisation (see Section 4.2.17)	Applicable. 80% of inertions are not continuous and use a pressure swing method consisting of pressuriation/vacuum cycles. For the remainder of cases, inertion is continuous as shock inertion is not feasible due to equipment design limitations.	BAT In Place

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20	5.1.2.4.4	BAT is to minimise the exhaust gas volume flows from distillations by optimising the layout of the condenser (see Section 4.2.20)	Applicable. All reactors have overhead condensers which minimise the VOC load to the LVI.	BAT In Place
21	21 5.1.2.4.5 BAT is to carry out liquid addition to vessels as bottom feed or with dip-leg, unless reaction chemistry and/or safety		Applicable. Liquid addition to vessels are via dip-pipe or diverted to vessel walls.	BAT In Place
22	5.1.2.4.6	BAT is to minimise the accumulation of peak loads and flows and related emission concentration peaks by, e.g. a) Optimisation of the production matrix b) application of smoothing filters (see Section 4.3.5.16 and also Section 4.3.5.13)	 Applicable. The sequence of gas evolved during processes are assessed as part of the Zurich Hazard Analysis (PHA tool). This is a critical evaluation stage of whether a new process is suitable for manufacturing at NRL. The calorific nature of any off-gases is also assessed in terms of impact upon the site's LVI 	BAT In Place

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			 Liquid flame arrestors present at the outlet of the Production Buildings and at the inlet to the LVI also provide a back-pressure which helps to even gas flow. 	
23	5.1.2.5.1	BAT is to avoid mother liquors with high salt content or to enable the work-up of mother liquors by application of alternative separation techniques (e.g. membrane process, solvent based process, reactive extraction, or omit intermediate isolation) (see BREF Section 4.2.24).	Not Applicable. There are individual process steps that have waste streams having a high salt content following phase separations or acid to base reactions. These are typically routed off-site for incineration. The most efficient process unit operations, including separation techniques are identified for each process at the Chemical and Analytical stage.	Not Applicable
24	5.1.2.5.2	BAT is to apply countercurrent product washing where the production scale justifies the introduction of the technique where feasible (see BREF Section 4.2.22).	Applicable. Counter-current product washing is employed in a process within Production Building 2, allowing the recovery and reuse of solvents.	BAT In Place
25	5.1.2.5.3	BAT is to apply water-free vacuum generation where feasible (see BREF Sections 4.2.5 to 4.2.7).	Applicable. Vacuum generation systems on site are either liquid vacuum pumps, once-through oil vacuum pumps or else dry running vacuum pumps.	BAT In Place

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26	5.1.2.5.4	For batch processes, BAT is to establish clear procedures for the determination of the desired end point of the reaction (for an example, see Section 4.2.23).	Applicable. The method for determining the end-point of reaction is specified in the Master Manufacturing Procedure for each process and a sign-off is subsequently required in the associated Manufacturing Batch Record.	BAT In Place
27	5.1.2.5.5	BAT is to apply indirect cooling (see Section 4.2.9).	Applicable. The site has the following main indirect cooling systems: - 2 × Glycol Chillers: Provide production process cooling (Total cooling capacity of 4 MW thermal, operating range of -25°C to -19°C; Ammonia is the refrigerant in the lead chiller) - 2 × Chilled water Chillers: Provide production and HVAC cooling (Total cooling capacity of 2.4 MW thermal; operating range of 5°C to 11°C; Ammonia is the refrigerant in the lead chiller) - 1 twin evaporative cooling tower: This provides production and utility system cooling (Total cooling capacity of 21,000 MW thermal; operating range 25°C to 30°C) - SSF (Small Scale Facility) Dowtherm Chiller for process cooling: Total cooling capacity of 120 kW and cools to -25°C	BAT In Place

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28	5.1.2.5.6	BAT is to apply a pre-rinsing step prior to rinsing/cleaning of equipment to minimise organic loads in wash-waters (see Section 4.2.12).	Applicable. Pre- and post-campaign cleaning is in place for production equipment using a suitable solvent to remove any previous production from the production train. This solvent waste is typically routed for on-site incineration with heat recovery; or in some cases, it may be routed off-site for incineration. Subsequent water washes are not typically employed. Where this does happen the waste is typically routed for off-site incineration.	BAT In Place
29	5.1.2.6	BAT is to assess the options and to optimise the energy consumption (for examples, see Sections 4.2.11 and 4.2.20).	 Applicable. The site's energy efficiency management system is incorporated in the certified EMS system ISO 14001. This system incorporates all of the energy planning requirements of ISO 50001 and meets the requirements of EU (Energy Efficiency) Regulations 2014 (S.I. 426 of 2014), as amended Steam at average rate of 7,500 kg/h is produced from the site's Liquid Vapour Incinerator. The site implemented a project to recover low-grade heat from the scrubber section of the Liquid Vapour Incinerator (LVI) using a new heat exchanger and distributed the recovered heat to air conditioning 	BAT In Place

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			 units on site Exhaust air from the WWTP Aeration, which is at an average temperature of 30°C, is collected in the waste gas header system and provides combustion air to the site's LVI Heat is recovered from the air compressors and used for the compressed air dryers 	
	5.2.1	BAT for Mass balances and process waste stream analysis		
30	5.2.1.1.1	BAT is to establish mass balances for VOCs (including CHCs), TOC or COD, AOX or EOX and heavy metals on a yearly basis (see Sections 4.3.1.4, 4.3.1.5 and 4.3.1.6).	Not Applicable. Mass balances for processes are determined as part of the Zurich Hazard Analysis (ZHA). Updates are made if there any changes to the process and the ZHA are reviewed on a five year cycle. The requirement for an annual solvent mass balance as part of an updated IE Licence is anticipated.	Scheduled for Implementation – Next AER following IE Licence review update
31	5.2.1.1.2	BAT is to carry out a detailed waste stream analysis in order to identify the origin of the waste stream and a basic data set to enable management and suitable treatment of exhaust gases, waste water streams and solid residues (see Section 4.3.1.1).	Applicable. All waste streams from processes have been quantified as recorded in Master Manufacturing Procedures and Process Mass Balances thereby allowing suitable management and treatment of these streams, which is also based upon Process Risk Assessment, Safety Data Sheets and Safety Testing	BAT In Place

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				Information.	
32	5.2.1.1.3	BAT is to assess at least the parameters 5.1 for waste water streams, unless the seen as irrelevant from a scientific point Section 4.3.1.2).	parameter can be	Applicable. The parameters listed in Table 5.1 Section 5.2.1.1.3 of the BREF are specified in the site's Master Manufacturing Procedures and the Process Mass Balances.	BAT In Place
		Parameter			
		Volume per batch		Standard	
		Batches per year			
		Volume per day			
		Volume per year			
		COD or TOC	Standard		
		BOD,			
		pH			
		Bioeliminability			
		Biological inhibition, including nitrification			
		AOX			
		CHCs	4		
		Solvents	4		
		Heavy metals	4		
		Total N Total P	Where it is expected		
		Chloride	1		
		Bromide	1		
		SO. ³	1		
		Residual toxicity	1		

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33	5.2.1.1	For emissions to air, BAT is to monitor the emission profile which reflects the operational mode of the production process	Applicable. There is continuous monitoring of emissions to atmosphere from the site's Liquid Vapour Incinerator (LVI) and Solid Waste Incinerator (SWI) as per the site's IE Licence requirements	BAT In Place
34	5.2.1.1	BAT is to individually monitor substances with ecotoxicological potential if such substances are released	Applicable. Individual monitoring is performed for the following substances emitted to atmosphere from the site's LVI and SWI in compliance with Schedule C.1.2 of the site's IE Licence: VOC, Total particulates, Carbon monoxide, Hydrogen chloride, Oxides of sulphur, Hydrogen fluoride, Hydrogen bromide, Dioxin and Heavy Metals.	BAT In Place
35	5.2.2	BAT for Re-use of Solvents BAT is to re-use solvents as far as purity requirements (e.g. cGMP requirements) allow, by: a) Use the solvent from previous batches of a production campaign for future batches (see BREF Sections 4.3.3 to 4.3.4) b) Collect spent solvents for on or off-site purification and re-use (see BREF Sections 4.3.3 to 4.3.4).	Applicable. - While currently, onsite recovery of solvent is not in operation due to changes in the site's product portfolio resulting in insufficient volumes of suitable solvents being consumed, there is direct recovery and resue within individual processes in the production buildings. Also the onsite recovery unit is available for future use depending upon production portfolio demands	BAT In Place

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		c) collecting spent solvents for on-site or off-site utilisation of the calorific value (see Section 4.3.5.7)	 Overhead condensers are in place that recycle the solvent back into the vessel, thereby reducing the VOC load requiring treatment In the event that dichloromethane (DCM) is used in a process within Production Building 1 (PB1), the waste gas stream containing DCM along with those from the storage DCM vessels, are directed to a cryogenic skid to condense the DCM vapours before being directed to the site's LVI The site's LVI can accept organic solvent within a specific caloric value range for utilisation 	
	5.2.3.	Treatment of exhaust gases		
36	5.2.3.1	BAT is to select VOC recovery abatement techniques according to the flow scheme in Figure 5.1	 Applicable. Overhead condensers are used in reactors and in the majority of dryers In the event that dichloromethane (DCM) is used in a process within Production Building 1 (PB1), the waste gas stream containing DCM along with those from the storage DCM vessels, are directed to a cryogenic skid to condense the DCM vapours before being directed to the site's LVI All process waste gas headers are treated by the site's 	BAT In Place

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			- Caustic scrubbers are used on the rich vent waste gas header system onsite to neutralise acid gases from a number of processes (run on a campaign basis and not continuously) before being directed to the site's LVI. There are two caustic scrubbers in each of Production Building 1 and PB1A; one caustic scrubber in Production Building 2 and the Small Scale Facility building. There is also a caustic scrubber on the flue gas cleaning system of the Liquid Vapour Incinerator, which is used to neutralise acid gases formed during the combustion process	
37	5.2.3.1.2	BAT is to reduce emissions to the levels given in Table 5.2 where non-oxidative VOC recovery or abatement techniques are applied (see Sections 4.3.5.6, 4.3.5.11, 4.3.5.14, 4.3.5.17, 4.3.5.18)	Not applicable. All process waste gas streams are directed to the site's Liquid Vapour Incinerator before being discharged to atmosphere.	Not applicable
38	5.2.3.1.3	BAT is to reduce VOC emissions to the levels given in Table 5.3 where thermal oxidation/incineration or catalytic oxidation are applied (see Sections 4.3.5.7, 4.3.5.8, 4,3,5,18)	Not applicable. The VOC emission limits for the site's LVI and SVI are specified in Schedule B.1 of the site's IE Licence and reflect the emission limit values for waste incineration plants specified in Part 3 of Annex VI to the Industrial Emissions Directive	Not applicable

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BAT No.	BAT reference Number	BAT Statement					Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		Thermal oxidation/incineration or catalytic oxidation Total organic C The averaging time relates to relate to dry gas and Nm² Table 5.3: BAT associated emission leverallytic oxidation		or se Section 5.2.		eration or	2010/75/EU. The site will assess compliance with the BAT Conclusions for Waste Incineration issued in November 2019. The site has four years from the date of issue of these BAT Conclusion to be compliant.	
	5.2.3.2	Recovery/abatement o	f NOx					
39	5.2.3.2.1	Recovery/abatement of NOx For thermal oxidation/incineration or catalytic oxidation, BAT is to achieve emission levels given in Table 5.5 and, where necessary, to apply a DeNox system (e.g. SCR or SNCR) or two stage combustion to achieve such levels (see Section 4.3.5.7 and 4.3.5.19)			n Table 5.5 a em (e.g. SCR	and, or	 Not applicable. All process waste gas streams are directed to the site's Liquid Vapour Incinerator before being discharged to atmosphere. The NOx emission limits for the site's LVI and SVI are specified in Schedule B.1 of the site's IE Licence and reflect the emission limit values for waste incineration plants specified in Part 3 of Annex VI to the Industrial Emissions Directive 2010/75/EU. The site will assess compliance with the BAT Conclusions for Waste Incineration issued in November 2019. The site has four years from the date of issue of these BAT Conclusion to be compliant. 	Not applicable

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BAT No.	BAT reference Number	BAT Statement				Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		Source	Average mass flow kg/hour*	Average concentration mg/m³°	1 Comment		
		Chemical production processes, e.g. nitration, recovery of spent acids	0.03 – 1.7	7 – 220** or	The lower end of the range relates to low inputs to the scrubbing system and scrubbing with H ₂ O. With high input levels, the lower end of the range is not achievable even with H ₂ O ₂ as the scrubbing medium		
		catalytic oxidation Thermal oxidation/incineration,	0.1 – 0.3	13 - 50 ***	Lower range with SCR,		
		catalytic oxidation, input of nitrogenous organic compounds * NO _X expressed as NO ₂ , the averagin Levels relate to dry gas and Nm ³ *** Levels relate to dry gas and Nm ³ Table 5.5: BAT associated NO _X emiss		25 – 150°** the emission profile (s	upper range with SNCR		
		Table 5.5; DAT associated NO _X emiss	sion levels				
40	5.2.3.2.2	For exhaust gases from				Not Applicable.	Not applicable
		is to achieve the NOx en where necessary to app scrubbing or scrubber of H ₂ O and/or H ₂ O ₂ to ach	oly treati cascades	ment techr with scrub	niques such as ober media such as	All process waste gas streams are directed to the site's Liquid Vapour Incinerator before being discharged to atmosphere.	

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
41	5.2.3.3	Recovery/abatement of HCl, Cl ₂ and HBr/Br ₂ BAT is to achieve HCl emission levels of 0.2-7.5 mg/m³ or 0.001-0.08 kg/hour and, where necessary, to apply of one or more scrubbers using H ₂ O or NaOH in order to achieve such levels (see Section 4.3.5.3) BAT is to achieve Cl ₂ emission levels of 0.1 – 1 mg/m³ and where necessary, to apply techniques such as adsorption of the excess chlorine (see Section 4.3.5.5) and/or scrubbing with scrubbing media such as NaHSO ₂ in order to achieve such levels (see Section 4.3.5.2) BAT is to achieve HBr emission levels <1 mg/m³ and, where necessary, to apply scrubbing media such as H ₂ O or NaOH in order to achieve such levels (see Sections 1.1.1, 4.3.5.4)	 Not applicable. All process waste gases are directed to the site's LVI before being discharged to atmosphere The HCl emission limits for the site's LVI are specified in Schedule B.1 of the site's IE Licence and reflect the emission limit values for waste incineration plants specified in Part 3 of Annex VI to the Industrial Emissions Directive 2010/75/EU. The site will assess compliance with the BAT Conclusions for Waste Incineration issued in November 2019. The site has four years from the date of issue of these BAT Conclusion to be compliant. No emission limit values for Cl₂ are specified in the site's IE Licence or in Part 3 of Annex VI to the Industrial Emissions Directive 2010/75/EU The HBr emission limits for the site's LVI are specified in Schedule B.1 of the site's IE Licence. There are no emission limit values for HBr in Part 3 of Annex VI to the Industrial Emissions Directive 2010/75/EU Caustic scrubbers are used on the rich vent waste gas header system onsite to neutralise acid gases from a number of processes (run on a campaign basis and not continuously) before being directed to the site's LVI. There are two caustic scrubbers in each of Production 	Not applicable

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			Building 1 and PB1A; one caustic scrubber in Production Building 2 and the Small Scale Facility building. There is also a caustic scrubber on the flue gas cleaning system of the Liquid Vapour Incinerator, which is used to neutralise acid gases formed during the combustion process	
42	5.2.3.4	NH ₃ emission levels BAT is to achieve NH ₃ emission levels of $0.1-10 \text{ mg/m}^3$ or $0.001\text{-}0.1 \text{ kg/hour}$ and, where necessary, to apply scrubbing with scrubbing media such as H ₂ 0 or acid in order to achieve such levels (see Section 4.3.5.20) BAT is to achieve NH ₃ slip levels from SCR or SNCR of <2 mg/m ³ or <0.02 kg/hour (see Section 4.3.5.7)	Not applicable. NH₃ is not generated from production processes on site.	Not applicable
43	5.2.3.5	Removal of SOx from exhaust gases BAT is to achieve SOx emission levels of 1-15 mg/m 3 or $0.001-0.1$ kg/hour and, where necessary, to apply scrubbing media such as H_2O or NaOH in order to achieve such levels (see Section 4.3.5.21).	 Not applicable. All process waste gases are directed to the site's LVI before being discharged to atmosphere SOx emission limits for the site's LVI are specified in Schedule B.1 of the site's IE Licence and reflect the emission limit values for waste incineration plants specified in Part 3 of Annex VI to the Industrial Emissions Directive 2010/75/EU. The site will assess compliance with the BAT Conclusions for Waste Incineration issued in 	Not applicable

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			November 2019. The site has four years from the date of issue of these BAT Conclusion to be compliant.	
44	5.2.3.6	Removal of particulates from exhaust gases BAT is to achieve particulate emission levels of 0.05 – 5 mg/m³ or 0.001 – 0.1 kg/hour and, where necessary, to apply techniques such as bag filters, fabric filters, cyclones, scrubbing, or wet electrostatic precipitation (WESP) in order to achieve such levels (see Section 4.3.5.22)	 Not applicable. All process waste gases are directed to the site's LVI before being discharged to atmosphere Particulates (dust) emission limits for the site's LVI are specified in Schedule B.1 of the site's IE Licence and reflect the emission limit values for waste incineration plants specified in Part 3 of Annex VI to the Industrial Emissions Directive 2010/75/EU. The site will assess compliance with the BAT Conclusions for Waste Incineration issued in November 2019. The site has four years from the date of issue of these BAT Conclusion to be compliant. 	Not applicable
45	5.2.3.7	Removal of free cyanides from exhaust gases BAT is to remove free cyanides from exhaust gases, and to achieve a waste gas emission level of 1 mg/m³ or 3 g/hour as HCN (see Section 4.3.6.2)	Not applicable. - All process waste gases are directed to the site's LVI before being discharged to atmosphere - Free cyanides are not anticipated to be generated from the site's production processes	Not applicable

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	5.2.4	Management and treatment of waste water streams		
	5.2.4.1	Typical waste water streams for segregation, pretreatment or disposal		
46	5.2.4.1.1	BAT is to segregate and pretreat or dispose of mother liquors from halogenations and sulphochlorinations (see Sections 4.3.2.5, 4.3.2.10)	Applicable. Halogenations are performed on site and such related mother liquors are sent off-site for incineration.	BAT In Place
47	5.2.4.1.2	BAT is to pretreat waste water streams containing biologically active substances at levels which could pose a risk either to a subsequent waste water treatment or to the receiving environment after discharge (see Sections 4.3.2.6, 4.3.7.5, 4.3.7.9, 4.3.8.13 and 4.3.8.18)	Not Applicable. No biologically active wastewater streams are generated.	Not applicable
48	5.2.4.1.3	BAT is to segregate and collect separately spent acids, e.g. from sulphonations or nitrations for on-site or off-site recovery or to apply BAT given in 5.2.4.2 (see Sections 4.3.2.6, 4.3.2.8)	Not Applicable. Waste acids are not generated from sulphonations or nitrations on site. Waste acids can be accepted in relatively small amounts for on-site wastewater treatment (depending on the process that generated the waste acid). More typically waste acids arising from production processes are drummed up and shipped off-site for incineration.	Not Applicable

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	5.2.4.2	Treatment of waste water streams with relevant refractory organic load		
49	5.2.4.2.1	For the purposes of pretreatment, BAT is to classify organic loading as follows: Refractory organic loading is not relevant if the waste water streams show a bioeliminability of greater than about 80-90% (see Sections 4.3.7.6, 4.3.7.7, 4.3.7.8). In cases with lower bioeliminability, the refractory organic loading is not relevant if it is lower than the range of about 7.5 -40 kg TOC per batch or per day (see Sections 4.3.7.10, 4.3.7.12 and 4.3.7.13).	Applicable. Information on bioeliminability is found within Novartis GHS Safety Data Sheet data from the Novartis Corporate HSE database 'KSO'; information from Process Mass Balances; and Process Risk Assessments.	BAT In Place
50	5.2.4.2.2	BAT is to segregate and pretreat waste water streams containing relevant refractory organic loadings according to the criteria given in Section 5.2.4.2.1	Applicable. Processes are assessed (as part of HSE assessment in change control) to ensure that any aqueous waste proposed to be sent to the WWTP will not negatively impact its operation. Only lightly contaminated wastewater is allowed for wastewater treatment and off-site thermal treatment is used for aqueous wastewater streams that contain non-biodegradable or toxic components. A decision flow chart is used onsite to assess which waste waters can be sent to the WWTP.	BAT In Place

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
51	5.2.4.2.3	For the segregated waste water streams carrying a relevant refractory organic load according to Sections 5.2.4.2.1, BAT is to achieve overall COD elimination rates for the combination of pretreatment and biological treatment of >95% (see Section 4.3.8.9)	Not Applicable. Only lightly contaminated wastewater is allowed for wastewater treatment and off-site thermal treatment is used for aqueous wastewater streams that contain non-biodegradable or toxic components. A decision flow chart is used onsite to assess which waste waters can be sent to the WWTP.	Not Applicable
52	5.2.4.3	Removal of solvents from waste water streams BAT is to recover solvents from waste water streams for onsite or off-site reuse, using techniques such as stripping, distillation/rectification, extraction or combinations of such techniques, where the costs for biological treatment and purchase of fresh solvents are higher than the costs for recovery and purification (see Section 4.3.7.18) BAT is to recover solvents from waste water streams in order to use the calorific value if the energy balance shows that overall natural fuel can be substituted (see Section 4.3.5.7)	Applicable. Prior to the introduction of a new process to the site an assessment is performed as to whether solvent recovery is technically feasible, either within the process or in the site's solvent recovery unit. The assessment takes into account the production plan for the process (a short production run is typically less likely to incorporate solvent recovery).	BAT In Place

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	5.2.4.4	Removal of halogenated compounds from waste water streams		
53		BAT is to remove purgeable CHCs from waste water streams, e.g. by stripping, rectification or extraction and to achieve sum concentrations <1 mg/l in the outlet from pretreatment or to achieve sum concentrations <0.1 mg/l in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Sections 4.3.7.18, 4.3.7.19, 4.3.7.20)	 Applicable. In terms of the halogenated compounds used on site: Methyl bromide: This substance is used in very small quantities onsite and is consumed in the reactions where it is used Methylene chloride: This substance is used as a solvent however it is not stored as a bulk solvent due to the quantities used. A cryogenic skid is used when Methylene chloride is present in a process and any condensed solvent is sent for off-site disposal Liquid solvent waste for onsite incineration is analysed regularly to confirm that the concentration of organohalogens is not greater than 1% 	BAT In Place
54	5.2.4.4.2	BAT is to pretreat waste water streams with significant AOX loads and to achieve the AOX levels given in Table 5.6 in the inlet to the on-site biological WWTP or the inlet to the municipal sewerage system (see Section 4.3.7.14)	 Applicable. Only lightly contaminated wastewater is allowed for wastewater treatment and off-site thermal treatment is used for aqueous wastewater streams that contain non-biodegradable or toxic components. Monitoring of AOX is to be performed in compliance with 	Will Be - End of Aug 2020 (monitoring frequency) & by issue date of revised IE Licence

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			the Common Waste Water and Waste Gas BAT Conclusions. The requested AOX BAT-AEL in relation to these BAT Conclusions is 1.0 mg/l at the outlet from the site's WWTP (emission point reference no. 100).	(to relevant EN standard)
55	5.2.4.5	Pretreatment of waste water streams containing heavy metals BAT is to pretreat waste water streams containing significant levels of heavy metals or heavy metal compounds from processes where they are used deliberately and to achieve the heavy metal concentrations given in Table 5.7 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.22)	 Applicable. Only lightly contaminated wastewater is allowed for wastewater treatment and off-site thermal treatment is used for aqueous wastewater streams that contain non-biodegradable or toxic components. Filtration is applied to remove the metallic catalysts used in processes Monitoring for Cr, Ni and Zinc is to be performed in compliance with the Common Waste Water and Waste Gas (CWW & WG) BAT Conclusions The requested BAT-AELs for Cr, Ni and Zn in compliance with these BAT Conclusions are 5 μg/l, 5 μg/l and 300 μg/l respectively Given the annual mass emission of Cu the BAT-AELs specified in the CWW & WG BAT conclusion are not applicable 	Will Be - End of Aug 2020 (monitoring frequency) & by issue date of revised IE Licence (to relevant EN standards)

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
56	5.2.4.6	Destruction of free cyanides BAT is to recondition waste water streams containing free cyanides in order to substitute raw materials where technically possible (see Section 4.3.6.2) BAT is to: a) pretreat waste water streams containing significant loads of cyanides and to achieve a cyanide level of 1 mg/l or lower in the treated waste water stream (see Section 4.3.6.2) or to b) enable safe degradation in a biological WWTP (see Section 4.3.6.2 under Applicability)	Not Applicable. There are no wastewater streams containing free cyanides.	Not Applicable.
57	5.2.4.7	Biological waste water treatment After the application of BAT given in Sections 5.2.4.1, 5.2.4.2, 5.2.4.3, 5.2.4.4 and 5.2.4.5 (management and treatment of waste water streams), BAT is to treat effluents containing a relevant organic load, such as waste water streams from production processes, rinsing and cleaning water, in a biological WWTP (see Sections 4.3.8.6 and 4.3.8.10).	Applicable. Lightly contaminated waste water is directed to the site's WWTP, which utilises an activated sludge biological system to treat the waste water.	BAT In Place

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
58	5.2.4.7.1	BAT is to ensure that the elimination in a joint waste water treatment is overall not poorer than in the case of on-site treatment. This is realised by regular degradability/bioeliminability testing (see Section 4.3.8.5).	Not Applicable. A joint waste water treatment plant is not used by the site.	Not Applicable
59	5.2.4.7.2	Elimination rates and emission levels BAT is to take full advantage of the biological degradation potential of the total effluent and to achieve BOD elimination rates above 99% and yearly average BOD emission levels of 1-18 mg/l. The levels relate to the effluent after biological treatment without dilution, e.g. by mixing with cooling water (see Section 4.3.8.11). BAT is to achieve the emission levels given in Table 5.8.	Not Applicable. BAT-AELs from the site's WWTP waste water emissions are specified in the Common Waste Water and Waste Gas BAT Conclusions.	Not Applicable
60	5.2.4.8	Monitoring of the total effluent BAT is to regularly monitor the total effluent to and from the biological WWTP measuring at least the parameters given in Table 5.1 (see Section 4.3.8.21)	Not Applicable. Monitoring of effluent to and from the site's WWTP is in compliance with the site's IE Licence and will be in compliance with the monitoring requirements of the CWW & WG BAT Conclusions.	Not Applicable

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BAT No.	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
61	5.2.4.8.1	BAT is to carry out regular biomonitoring of the total effluent after the biological WWTP where substances with ecotoxicological potential are handled or produced with or without intention (for examples, see Sections 4.3.8.18 and 4.3.8.19)	Applicable. Monitoring of substances from the site's WWTP is in compliance with the site's IE Licence and in compliance with the toxicity monitoring requirements of the CWW & WG BAT Conclusions.	BAT In Place
62	5.2.4.8.2	BAT is to apply online toxicity monitoring in combination with online TOC measurement if residual acute toxicity is identified as a concern, for examples see Sections 4.3.8.7 and 4.3.8.20	Not Applicable. Acute toxicity is not identified as a concern for the site's WWTP effluent emissions. These emissions are monitored annually for toxicity in compliance with the site's IE Licence.	Not Applicable
63	5.3	Environmental Management BAT is to implement and adhere to an Environmental Management System (EMS) that incorporates, as appropriate to individual circumstances, the following features (see Chapter 4): - definition of an environmental policy for the installation by top management (commitment of the top management is regarded as a precondition for a successful application of other features of the EMS) - planning and establishing the necessary procedures - implementation of the procedures, paying	Applicable. The site is certified to the environmental management system ISO 14001:2015.	BAT In Place

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No. r	BAT reference Number	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		particular attention to structure and responsibility training, awareness and competence communication employee involvement documentation efficient process control maintenance programme emergency preparedness and response safeguarding compliance with environmental legislation checking performance and taking corrective action, paying particular attention to monitoring and measurement (see also the Reference document on Monitoring of Emissions) corrective and preventive action maintenance of records independent (where practicable) internal auditing in order to determine whether or not the environmental management system confirms to planned arrangements and has been properly implemented and		

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BAT No.	BAT reference Number		Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		maintained • review by top management		

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