

Attachment-4-7-2i-BREF-Organic Fine Chemicals

BREF Document for the Manufacture of Organic Fine Chemicals, August 2006

BAT No.	BAT reference Number	BAT Statement	Applicability Assessment	State technique and 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).	Yes	Environmental, health and safety considerations have been incorporated into the design process through specific EHS design reviews, ATEX reviews, HAZOPS etc. In terms of environmental and sustainability a construction environmental management plan is adhered to during any construction at the site. An integrated environment, health and safety management system is in place at the facility which is based on ISO14001 and ISO45001. These ensure that the process is designed with best industry practice applied.

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2	5.1.1.1	<p>BAT is to develop new processes as follows (see Section 4.1.1):</p> <p>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)</p> <p>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).</p> <p>c) to avoid the use of auxiliary substances (e.g. solvents, separation agents, etc. see e.g. Section 4.1.4.2)</p> <p>d) to minimise energy requirements in recognition of the associated environmental and economic impacts. Reactions at ambient temperatures and pressures should be preferred</p> <p>e) to use renewable feedstock rather than depleting, wherever technically and economically practicable</p> <p>f) to avoid unnecessary derivatisation (e.g. blocking or protection groups)</p> <p>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)</p>	Yes	<p>All processes at the facility have been designed in order to ensure maximum use of input materials and minimal loss of product. This is achieved through SOPs, and the Manufacturing Control System (MCS), which controls all process parameters.</p> <p>The manufacturing process at Alexion is an aqueous based activity and the inventory of chemical materials stored on site is small. However, a small number of substances used on site are toxic to human health and the environment (refer to Attachment-4-6-2). Potential for accidents, releases, explosions and fires are minimised through use of correct containment, storage and dispensing systems. On-going review as to whether any of these substances can be eliminated or replaced with less toxic, flammable, etc. alternatives is carried out at the site.</p> <p>The WFI stills will discharge into WFI storage tanks. The WFI storage tanks will be maintained at temperatures above 85degC. The tanks will be provided with WFI supply skids equipped with circulation pumps for hot and ambient WFI supply. Hot WFI will be supplied to the CIP skids and ambient WFI will be supplied to the media prep, harvest, buffer prep and wash areas.</p>
3	5.1.1.2	<p>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).</p>	Yes	<p>The operation of proposed development is implemented under strict accordance under the Safety, Health and Welfare at Work (Construction) regulations, 2013 S.I. 291 of 2013 and the Safety, Health and Welfare at Work Act, 2005, during construction and operational phases respectively.</p> <p>Environmental, health and safety considerations are incorporated into the design process through specific EHS design reviews, ATEX reviews, HAZOPS or other Process Hazard Analysis (PHA) tools.</p>

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4	5.1.1.2	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.	Yes	The existing and proposed processes at the site has undergone / will undergo EHS design reviews, ATEX reviews, HAZOPs/PHA reviews to ensure that the relevant control measures are in place to avoid any hazards and plant operability issues which may or may not lead to environmental impact. Therefore the techniques outlined in the BREF and other techniques will be considered to ensure process safety.
5	5.1.1.2	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).	Yes	The existing and proposed processes at the site have undergone / will undergo EHS design reviews, ATEX reviews, HAZOPs/PHA reviews to ensure that the relevant control measures are in place to avoid any hazards and plant operability issues which may or may not lead to environmental impact, including any risks that may be associated with the handling and storage of hazardous substances.
6	5.1.1.2	BAT is to provide sufficient and adequate training for operators who handle hazardous substances (for an example, see Section 4.2.29).	Yes	Training and SOPs are provided for the operators of the facility in order to ensure proper handling and storage of hazardous materials.
	5.1.2	BAT for Minimisation of environmental impact		
7	5.1.2.1	BAT is to design new plants in such a way that emissions are minimised by applying techniques including the following (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)	Yes	Segregation of Hazardous waste is carried out at source with wastes sent for recovery or recycling under licensed contract, where possible. Extract air vents are located throughout the facility which emit spent fresh air which has been utilised in building(s) HVAC system. Air dispersion Modelling has been completed for site. Based on the modelling the facility has been designed to ensure that the predicted environmental concentrations are within the applicable air quality standard limit values. No large Organic Solvents present in processes. Only

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		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.		18-20% ethanol and 17-23% IPA are used in purification step, which is a closed system and will only lead to fugitive emissions during transfer only. Air-tightness testing of the Building envelopes has been / will be completed to limit air infiltration.
8	5.1.2.2	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).	Yes	All storage facilities are specified in order to be compatible to what is being stored. All process vessels are fitted with the required level alarms and switches in order to prevent overfills and unnecessary emissions. All process parameters are controlled by the MCS (Process Control System). Staff are trained and follow SOPs. The processes on site have undergone / will undergo HAZOPs to ensure that the necessary controls are in place in the case of deviations from the operating norms. The facility has been designed in order to allow for ease of and safe access for maintenance. An emergency response plan has been developed at the site. Fire fighting facilities and fire brigade access is in compliance with Part B of the Building Regulations.
9	5.1.2.2	BAT is to enable leakages to be quickly and reliably recognised (see Section 4.2.27).	Yes	Site-wide mitigation measures and spill control programme that is proposed in accordance with the IE Licence will apply to the facility. This will include on-going bund integrity and drain testing programme, environmental monitoring and management procedures for potentially polluting materials. The MCS as well as the appropriate periodic visual checks that will be implemented will allow leakages to be quickly and reliably recognised. All material transfer pipelines are located above ground.
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).	Yes	The internal process drainage system is/will be capable of safely retaining any spill and leakages. All chemicals and materials at the site are stored with containment as required in accordance with EPA guidelines. Spill kits are also available at the site in order to contain any potential spill or leakages.

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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).	Yes	A fire water runoff risk assessment has been carried out for the site in accordance with EPA guidance and is included in the IE licence application. Because the manufacturing process at Alexion is an aqueous based activity, the inventory of chemical material potentially stored on site is small and does not exceed any of the guideline thresholds for firewater retention. Furthermore, storage of all potentially polluting materials on the site will be bunded. Consequently, the risk assessment concluded that on-site emergency retention is not required. In addition the storm water system will contain an actuated valve arrangement to and contain any contamination event.
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.	Yes	(a) Loading and unloading which is carried out just south of the Biologics Manufacturing Building occurs on a harstanding area protected from leakage by draining to a contained system. Therefore any leakage runoff will be collected and stored. (b) All wastes are held in designated areas which are connected to the site system. Therefore any leakage run-off will be collected and stored. (c) The facility and the process is governed by SOPs and by the MCS, which controls all process parameters. Tanks are fitted with high level alarms to prevent overfilling. (d) Testing and inspection of tanks and pipelines will be carried out in accordance with the IE Licence. (e) Spill kits are provided throughout the site (f) Any bunds installed have been initially tested prior to use and will be tested thereafter in accordance with the requirements of the IE Licence. (g) All tanks at the site are fitted with overfill protection.
13	5.1.2.3	BAT is to contain and enclose sources and to close any openings in order to minimise uncontrolled emissions (see Section 4.2.14).	Yes	Direct process operations are aqueous based and do not generate any significant emissions of VOCs. Storage vessels are closed and contain conservation vents.
14	5.1.2.3	BAT is to carry out drying by using closed circuits, including condensers for solvent recovery (see Section	N/A	N/A

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		4.2.14).		
15	5.1.2.3	BAT is to keep equipment closed for rinsing and cleaning with solvents (see Section 4.2.14).	Yes	In order to maximise productivity, all of the major stainless steel vessels and processing equipment is cleaned via an automated system (Clean In Place or 'CIP'). The equipment is rinsed with purified water and residual soil is removed by use of recirculating cleaning solutions. This is an enclosed cleaning method.
16	5.1.2.3	BAT is to use recirculation of process vapours where purity requirements allow this (see Section 4.2.14).	N/A	N/A
17	5.1.2.4	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).	N/A	N/A
18	5.1.2.4	BAT is to ensure the airtightness of process equipment, especially of vessels (see Section 4.2.16).	Yes	All process vessels are and will be designed to be air tight for GMP purposes and will be subject to a routine maintenance and testing schedule.
19	5.1.2.4	BAT is to apply shock inertisation instead of continuous inertisation (see Section 4.2.17).	Yes	The ethanol and propanol day tanks have nitrogen inerting for safety and to prevent fugitive emissions.
20	5.1.2.4	BAT is to minimise the exhaust gas volume flows from distillations by optimising the layout of the condenser (see Section 4.2.20).	N/A	N/A
21	5.1.2.4	BAT is to carry out liquid addition to vessels as bottom feed or with dip-leg, unless reaction chemistry and/or safety considerations make it impractical (see Sections 4.2.15, 4.2.18). In such cases, the addition of liquid as top feed with a pipe directed to the wall reduces splashing and hence, the organic load in the displaced gas.	Yes	All additions of concentrated solvent to the buffer vessels in Purification will be via sub-surface dip-tube in Water for Injection (WFI).
22	5.1.2.4	If both solids and an organic liquid are added to a vessel, BAT is to use solids as a blanket in circumstances where the density difference promotes the reduction of the organic load in the displaced gas, unless reaction chemistry and/or safety considerations make it impractical (see Section 4.2.18).	N/A	N/A

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23	5.1.2.4	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 (see Section 4.3.5.17) b) application of smoothing filters (see Section 4.3.5.16 and also Section 4.3.5.13).	N/A	N/A
24	5.1.2.5	BAT is to avoid mother liquors with high salt content or to enable the work-up of mother liquors by the application of alternative separation techniques (see Section 4.2.24), e.g. a) membrane processes b) solvent-based processes c) reactive extraction d) or to omit intermediate isolation.	N/A	N/A
25	5.1.2.5	BAT is to apply countercurrent product washing where the production scale justifies the introduction of the technique (see Section 4.2.22).	N/A	N/A
26	5.1.2.5	BAT is to apply water-free vacuum generation (see Sections 4.2.5, 4.2.6 and 4.2.7).	Yes	Vacuum pumps in the Fill Finish filling line are water-free.
27	5.1.2.5	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).	Yes	SOPs have been / will be developed which outline the desired end point of the formulation reaction. The MCS will control recipe and all other process parameters.
28	5.1.2.5	BAT is to apply indirect cooling (see Section 4.2.9).	Yes	Indirect cooling is and will be achieved through Cooling Tower Water systems and Chilled Water systems.
29	5.1.2.5	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).	Yes	In order to maximise productivity, all of the major stainless steel processing equipment is cleaned via an automated system (Clean In Place or 'CIP'). The equipment is rinsed with purified water and residual soil is removed by use of recirculating cleaning solutions. All aqueous waste water is recovered from the cleaning systems and directed to the process drain.

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30	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).	Yes	The design of the facility will be developed in line with the requirements of the European Union (Energy Performance of Buildings) Regulations 2012, S.I. No. 243 of 2012. Part 2 of these Regulations (Alternative Energy Systems) applies to the design of any building for which a planning application is made, or a planning notice is published, effective since 9 January 2013
	5.2.1	BAT for Mass balances and process waste stream analysis		
31	5.2.1.1	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).	Yes	Note: AOX, VOCs and heavy metals do not apply here to this site. The mass balance for TOC and COD for the site has been determined (mass balance for Biologics, limited TOC and COD from Fill Finish operations). It is noted that there is no extraction, wet oxidation, or incineration involved in the process.
32	5.2.1.1	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).	Yes	Waste water characterisation is carried out identifying waste water loads and their sources. Nature of the process leads to insignificant gaseous emissions and very low levels of solid waste (in the kg scale).
33	5.2.1.1	BAT is to assess at least the parameters given in Table 5.1 for waste water streams, unless the parameter can be seen as irrelevant from a scientific point of view (see Section 4.3.1.2).	Yes	A study has been carried out to determine the waste streams from the site and the current and expected flows and concentrations/loads of the relevant parameters. Discussions have been held with Irish water to ensure that Monksland WWTP and will continue during the licensing review process. Alexion currently monitors its waste water in accordance with its Trade Effluent Discharge Licence and will monitor its waste water in accordance the IE licence (see Attachment-7-3-1 for more details).
34	5.2.1.1	For emissions to air, BAT is to monitor the emission profile which reflects the operational mode of the production process (see Section 4.3.1.8).	Yes	From Air Dispersion Modelling Report: it is concluded that atmospheric emissions from the proposed facility will not have a significant impact on ambient air quality. Main air emissions (boilers only) will be monitored in

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				accordance with requirements of IE licence.
35	5.2.1.1	In the case of a non-oxidative abatement/recovery system, BAT is to apply a continuous monitoring system (e.g. FID), where exhaust gases from various processes are treated in a central recovery/abatement system (see Section 4.3.1.8).	N/A	N/A
36	5.2.1.1	BAT is to individually monitor substances with ecotoxicological potential if such substances are released (see Section 4.3.1.8).	Yes	Main emission to air points (boilers) will be monitored annually for nitrogen oxides and carbon monoxide.
37	5.2.1.1	BAT is to assess individual exhaust gas volume flows from process equipment to recovery/abatement systems (see Section 4.3.1.7).	N/A	N/A
	5.2.2	BAT for Re-use of Solvents		
38	5.2.2	BAT is to assess individual exhaust gas volume flows from process equipment to recovery/abatement systems (see Section 4.3.1.7).	Yes	The only solvents used in the purification process is an 18-20% solution of ethanol and 17-23% solution of propanol which will give rise to low level fugitive emissions only. It is a closed system but there may be fugitive emissions during transfer.
	5.2.3	BAT for Treatment of exhaust gases		
39	5.2.3.1	BAT is to select VOC recovery and abatement techniques according to the flow scheme in Figure 5.1.	Yes	The process is aqueous based so no large volume solvents are used. The only solvents used in the purification process is an 18-20% solution of ethanol and a 17-23% solution of propanol which will give rise to low level fugitive emissions only. It is a closed system but there may be fugitive emissions during transfer. There may also be some fugitive emissions from the use of IBCs containing ethanol and propanol. These emissions are expected to be minor.
40	5.2.3.1	BAT is to reduce emissions to the levels given in Table 5.2 where nonoxidative 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).	N/A	N/A
41	5.2.3.1	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,	N/A	N/A

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		4.3.5.8, 4.3.5.18).		
42	5.2.3.2	For thermal oxidation/incineration or catalytic oxidation, BAT is to achieve the NOX 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 Sections 4.3.5.7 and 4.3.5.19).	N/A	N/A
43	5.2.3.2	For exhaust gases from chemical production processes, BAT is to achieve the NOX emission levels given in Table 5.5 and, where necessary to apply treatment techniques such as scrubbing or scrubber cascades with scrubber media such as H ₂ O and/or H ₂ O ₂ to achieve such levels (see Section 4.3.5.1).	Yes	Given the results of the air Dispersion Modelling Assessment and the fact that it is predicted that there will be no significant impact to the air environment due to the proposed development, it is not required to employ specific mitigation measures in order to minimise or eliminate potential impact. The site will be governed by an Industrial Emissions Licence (IE Licence) from the EPA. Part II (9) of S.I. No. 137/2013 - Environmental Protection Agency (Industrial Emissions) (Licensing) Regulations 2013 sets out the statutory requirements for information to accompany a licence application.
44	5.2.3.3	BAT is to achieve HCl emission levels of 0.2 – 7.5 mg/m ³ or 0.001 – 0.08 kg/hour and, where necessary, to apply of one or more scrubbers using scrubbing media such as H ₂ O or NaOH in order to achieve such levels (see Section 4.3.5.3).	N/A	N/A
45	5.2.3.3	BAT is to achieve Cl ₂ emission levels of 0.1 – 1 mg/m ³ and, where necessary, to apply techniques such as absorption of the excess chlorine (see Section 4.3.5.5) and/or scrubbing with scrubbing media such as NaHSO ₃ in order to achieve such levels (see Section 4.3.5.2).	N/A	N/A
46	5.2.3.3	BAT is to achieve HBr emission levels <1 mg/m ³ and, where necessary, to apply scrubbing with scrubbing media such as H ₂ O or NaOH in order to achieve such levels (see Sections 1.1.1, 4.3.5.4).	N/A	N/A
47	5.2.3.4	BAT is to achieve NH ₃ emission levels of 0.1 – 10 mg/m ³ or 0.001 – 0.1 kg/hour and, where necessary, to apply scrubbing with scrubbing media such as H ₂ O	N/A	N/A

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		or acid in order to achieve such levels (see Section 4.3.5.20).		
48	5.2.3.4	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).	N/A	N/A
49	5.2.3.5	BAT is to achieve SO _x emission levels of 1 – 15 mg/m ³ or 0.001 – 0.1 kg/hour and, where necessary, to apply scrubbing with scrubbing media such as H ₂ O or NaOH in order to achieve such levels (see Section 4.3.5.21).	N/A	N/A
50	5.2.3.6	BAT is to achieve particulate emission levels of 0.05 – 5 mg/m ³ 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).	N/A	There will be no particulate emissions from the site.
51	5.2.3.7	BAT is to remove free cyanides from exhaust gases, and to achieve a waste gas emission level of 1 mg/m ³ or 3 g/hour as HCN (see Section 4.3.6.2).	N/A	N/A
	5.2.4	BAT for Management and Treatment of Waste water streams		
52	5.2.4.1	BAT is to segregate and pre-treat or dispose of mother liquors from halogenations and sulphochlorinations (see Sections 4.3.2.5, 4.3.2.10).	N/A	N/A
53	5.2.4.1	BAT is to pre-treat 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).	Yes	Treatment at source (comprising chemical inactivation) is to be provided to waste water streams potentially containing active cells in Level 2 of the Manufacturing Building.
54	5.2.4.1	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).	N/A	N/A

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55	5.2.4.2	For the purposes of pre-treatment, BAT is to classify organic loading as follows: Refractory organic loading is not relevant if the waste water stream shows 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).	N/A	N/A
56	5.2.4.2	BAT is to segregate and pre-treat waste water streams containing relevant refractory organic loadings according to the criteria given in Section 5.2.4.2.1.	N/A	N/A
57	5.2.4.2	For the segregated waste water streams carrying a relevant refractory organic load according to Section 5.2.4.2.1, BAT is to achieve overall COD elimination rates for the combination of pre-treatment and biological treatment of >95 % (see Section 4.3.8.9).	N/A	N/A
58	5.2.4.3	BAT is to recover solvents from waste water streams for on-site 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).	N/A	N/A
59	5.2.4.3	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).	N/A	N/A
60	5.2.4.4	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 of <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).	N/A	N/A

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61	5.2.4.4	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 in the inlet to the municipal sewerage system (see Section 4.3.7.14).	N/A	N/A
62	5.2.4.5	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).	N/A	N/A
63	5.2.4.6	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).	N/A	N/A
64	5.2.4.6	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).	N/A	N/A
65	5.2.4.7	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).	Yes	Wastewater from the site is and will be treated in Monksland WWTP. According to the 2017 annual environmental report for the WWTP, there is an organic capacity of 4,000PE available. Discussions have been held with Irish Water and will continue during the licensing review process to that waste water from the Alexion site will be treated appropriately.
66	5.2.4.7	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).	N/A	N/A

BAT No.	BAT reference Number	BAT Statement	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
67	5.2.4.7	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).	N/A	N/A
68	5.2.4.7	BAT is to achieve the emission levels given in Table 5.8.	N/A	N/A
69	5.2.4.8	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).	N/A	N/A
70	5.2.4.8	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).	N/A	N/A
71	5.2.4.8	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.	N/A	N/A

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