Environment Agency Permitting decisions

Bespoke Variation

We have decided to issue the variation for Gaskill Road, Speke Vaccines operated by Novartis Vaccines and Diagnostics Limited

The variation number is EPR/BS5401IK/V006

The permit number is EPR/BS5401IK

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

This variation is linked to two key changes as follows:

- Introduction of a new product to site 4.
- Introduction of new contained waste storage facilities on site 4.

Purpose of this document

This decision document:

- explains how the application has been determined
- provides a record of the decision-making process
- shows how all relevant factors have been taken into account
- justifies the specific conditions in the permit other than those in our generic permit template.

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Structure of this document

- **Annex 1 the decision checklist and Key Issues**

Annex 1: decision checklist

Aspect considered	Justification / Detail	Criteria met Yes
Receipt of submission		
Confidential information	A claim for commercial or industrial confidentiality has not been received.	✓
Operator		
Control of the facility	We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with EPR RGN 1 Understanding the meaning of operator.	✓
European Directives		
Applicable Directives	All applicable European Directives have been considered in the determination of the application.	✓
The site		
Extent of the site of the facility	There is no change to the installation boundary linked to this variation. Therefore no new plan has been included in this variation. It should be noted that main process operations on site 3 within installation boundary have ceased; however this permit variation is linked to new product on site 4. A partial surrender will follow separately for site 3 closure.	✓
Biodiversity, Heritage, Landscape and Nature Conservation	The application is within the relevant distance criteria of two statutory sites (one actual site Mersey Estuary with two designations) and 12 non-statutory sites (including 9 Local Wildlife sites, two Ancient Woodlands and one Local Nature Reserve). ***The formaldehyde emission to atmosphere is insignificant*** ***The formaldehyde and Cetyltrimethylammonium bromide (CTAB) emissions are to sewer and have been assessed as insignificant.*** ***As such environmental impact on above habitat sites is considered insignificant.***	✓
Environmental Risk Assessment and operating techniques		
Environmental risk	We have reviewed the operator's assessment of the environmental risk from the facility. The detail of the review is outlined in key issues section. **In brief all the atmospheric emissions linked to this variation change (formaldehyde) are assessed as insignificant** **The emissions to sewer linked to variation are also insignificant.** There are five new raw materials introduced with this variation – volumes and containers sizes are small – see AG062011A supporting document for annual usages. The containment means for each material is stated in Table 1.1 of AG060211 within specific media store facilities. Waste storage –The new site 4 facility consists of 7 metallic containers to store different waste types. A detailed assessment of the risks and control measures in place has been provided with schedule 5 submission and is reviewed in key issues section of this document For both the new process and the new storage facilities we consider the controls as satisfactory representing indicative BAT measures.	✓
Operating techniques	We have reviewed the techniques used by the operator and compared these with the relevant guidance notes. The operating techniques include : • AG060211 document section 1 for new product • AG060211 document section 2 for waste operations • Schedule 5 response covering measures to minimise CTAB and formaldehyde emissions to sewer and specific operating procedure for waste storage container usage 11-08 RA-34. • Operating in line with revised draft consent to discharge for S7 effluent emission complete with new formaldehyde limit of **25mg/m3.** We consider that they reflect indicative BAT after a review of techniques in line with sector guidance EPR 4.02.	✓
The permit conditions		
Odour alternative conditions	This application introduces no additional odour risk. As such the current odour permit conditions 3.4.1 and 3.4.2 are sufficient.	✓
Noise alternative conditions	We consider that the variation changes do not have the potential to cause noise and/or vibration that might cause pollution outside the site. There are no new extraction fans/noisy equipment installed. As such the current noise permit condition 2.9.1 is sufficient.	✓
Raw materials	5 new materials are added Sodium Citrate, CTAB, Formaldehyde, Polysorbate 80 and Barium Sulphate – details are provided in the key issues section. When the eventual old Fluvirin product is removed (within the new two years potentially) potential major environmental contaminants will be removed hence having a positive environmental impact (Thiomersal containing mercury), beta-propiolactone and nonylphenol ethoxylate	✓

Aspect considered	Justification / Detail	Criteria met Yes
Accident Management	There are no major new accident risks linked to this variation as the process is essentially the same but with new 5 raw materials. The H1 annex a) assessment provided with an additional application dated 15/08/11 gives a full assessment of all potential hazards whether linked to old or new product operations. With this variation there is potential for an additional element to an existing hazard entitled "Chemical or waste spillage from pipeline or during material handling" linked to spillage from loading/unloading containers to new waste metallic storage facilities. The schedule 5 provided additional information linked to major accidents and fugitive emissions management to minimise environmental impact linked to the waste storage facilities. Key actions include labelling, inspection, spill detection, metallic container containment with appropriate sump volumes, operating techniques methods to minimise spill outside waste facility containers and sealing of local manholes and spill management external to waste facility containers. In addition an operating technique has been provided with the schedule 5 for the waste storage facilities to ensure environmental impact minimisation. We have reviewed this document and accepted as satisfactory. In addition the schedule 5 question response provides an updated plan layout SK/0001 for waste storage facility with the position and volume of a collection sump which would contain any spills immediately in front of containers for main three waste containers with highest volumes of potentially hazardous materials (flammable, non-flammable and acid store). The key issues section of this document under environmental assessment heading provides more details linked to the waste storage facility.	
Fugitive Emissions	The H1 annex a) assessment provided with an additional application response dated 15/08/11. This covers generic fugitive emissions for the whole installation not linked to specifically to the new process. **New process** The new process has 5 new raw materials. Table 1.1 of Ref AG060211 details means of storage for 5 new raw materials – containers range from 1litre bottles to 20 L containers. All are stored in sealed containers in a dedicated store within site 3 warehouse and then brought to site 4 for usage. All materials are stored on hard standing areas. The addition of liquid components is via a secondary container which further minimises fugitive emission loss. In terms of process dispensing of formaldehyde this is carried out in an existing fume cupboard that is linked to A20 emission point which will contain formaldehyde fumes and minimise fugitive emissions. In conclusion the risk of fugitive emissions to air and sewer is negligible. **Waste storage facilities** Techniques for fugitive emission minimisation for waste storage facilities are as per accident management section above.	
Wastes	The expected additional waste volumes linked to the new process are as follows: • Hazardous Waste CTAB laden waste resin – treated as hazardous waste and undergoes high temperature incineration (1kg per batch and 260 kg per annum estimate) • Non-hazardous waste Barium Sulphate residue (5 kg per batch ; estimate 1,300 kg per annum) – inorganic salt which is not classified as hazardous under EC Directives treated as hazardous waste and undergoes incineration. The waste volume to sewer of effluent from new process is approximately 60 m3 per batch with residual formaldehyde and CTAB. This is not additional effluent volumes as it will replace equivalent mercury based effluent when processing old products. An environmental assessment of this effluent stream is detailed in key issues section below. The waste volumes are low. The operator functions within the highly regulated pharmaceutical field requiring strict process protocols and written operating procedures ensure process consistency and waste minimisation. The operator has submitted their Healthy Safety and Environment Management Procedure Index HSE M 101 including waste management guidance. In order to ensure indicative BAT measures are met related to waste minimisation a commissioning report improvement program requires a review of actual raw material and waste usage. As such the Environment Agency considers that the operator has put satisfactory steps in place for waste minimisation.	✓
Energy	The existing process is to be re-utilised without any process equipment changes. As such energy usage changes are negligible. The Resource Efficiency Planning Index annual response will capture annual energy consumption levels.	
Pre-operational conditions	Based on the information in the application, we consider that we do not need to impose pre-operational conditions.	
Improvement conditions	Based on the information on the application, we consider that we need to impose one improvement programme which is for the submission of a commissioning report including monitoring data linked to formaldehyde and CTAB emissions monitoring to be completed linked to sewer discharge point S7 (site 4) again to substantiate operator assessment that impact is insignificant in line with H1 screening criteria. It also requires a raw material and waste usage review.	✓

Aspect considered	Justification / Detail	Criteria met Yes
Emission limits	There are no new emission points linked to this application. The emissions for this variation, via existing emission points, are assessed as insignificant and as such there is no need for any new emission limit values.	✓
Monitoring	We have decided that there is no need for new monitoring linked to formaldehyde air emissions as assessment has concluded environmental impact is insignificant. The improvement condition has not covered this atmospheric emission as the usage is only 5 minutes per day and will be negligible Emissions to sewer via S7 for formaldehyde and CTAB emissions are assessed as having insignificant environmental impact. The improvement program IP13 as detailed later will provide initial commissioning monitoring evidence for all new emissions. However for formaldehyde the operator after a technology review (see key issues sections for details) has depended on inherent process control as opposed to additional "end of pipe" abatement for minimising emissions. As such limited monitoring (weekly for three months of new production monitoring once IP13 monitoring complete) for formaldehyde emissions to S7 is required; this is to show on-going consistent low emissions as per application estimates. Afterwards the permit table S 4.3 d) allows for the Environment Agency to review monitoring requirement in light of these initial monitoring returns. Formaldehyde monitoring technique is based on a UKAS accredited technique utilising Environment Agency Labs Spectrophotometric method. Table S4.3 d) is updated accordingly. Method detail was provided in an additional response dated 02/09/11. In addition the CTAB monitoring technique is currently being updated by the operator to ensure UKAS/Mcerts accreditation. This method will be submitted along with monitoring results with improvement IP13 response	✓
Reporting	The reporting of monitoring data requirements table S5.1 has not changed due to this variation. The limited monitoring data for S7 will be reporting monthly as required for all other effluent emissions data.	✓
Operator Competence		
Environment Management System	There is no known reason to consider that the operator will not have the management systems to enable it to comply with the permit conditions. The operator has a rigorous in house EMS which has been improved and updated recently leading to a reduction in the OPRA score. The decision was taken in accordance with RGN 5 on Operator Competence.	✓
Relevant Convictions	The National Enforcement Database has been checked to ensure that all relevant convictions have been declared. No relevant convictions were found. The operator satisfies the criteria in RGN 5 on Operator Competence.	✓
Financial provision	There is no known reason to consider that the operator will not be financially able to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.	✓

Key Issues of the decision

1. Introduction

This variation is linked to:

- **Introduction of a new product to site 4.**
- **Introduction of new contained waste storage facilities on site 4.**

The variation application is on the basis that both old and new influenza vaccine products will operate on a batch basis one after each other but never at the same time. The operator confirmed that this variation does not increase the installation total capacity for influenza vaccine production. One point clarified in the 15/08/11 final application response relates to 73,000,000 figures in one of the application forms related to plant capacity. The operated clarified this value is taken from the original BS5401IK permit application information and relates to the number of individual doses of product potentially manufactured at the facility. Normally the operator generates fewer doses per annum than this number and note that fill finish activities are now undertaken at a sister site in Europe. This installation manufactures bulk vaccine that if filled equates to the above number of doses.

The operator has based the assessment on 260 days of operation per annum which is at the top end of realistic annual production.

In terms of actual equipment changes the following provides a summary:
New process
No process equipment changes. The material handling for liquid component containers will be placed in existing secondary containers to allow addition to the process with minimal changes
Waste storage containers
Seven bespoke waste storage containers to be added each with a specific purpose as detailed in key issues section; sealing of two surface water manholes near the waste containers for prevention of discharge to surface water.

New product introduction
After initial research campaigns in 2009 and 2010 of a modified influenza process , the operator wishes to progress further development runs (excluded under EPR Regulations) within 2011 (runs in August, September and November 2011) followed by readiness for commercial production form 2012 onwards. Data from the initial development stage batch campaigns have been utilised for formaldehyde emissions to sewer.

The verification of EPR regulations related to research and development activities is as follows:

Schedule 1

Application of activities falling within Sections 1.1 to 6.9 of Part 2

3. An activity is not to be taken to be an activity falling within Sections 1.1 to 6.9 of Part 2 of this Schedule if it is—

(c) carried on at an installation or by means of Part A mobile plant or Part B mobile plant solely used for research, development and testing of new products and processes;

As such the operator is pursuing the initial August/September 2011 campaign legally without a permit whilst at the same time pursuing a permit variation to ensure readiness to carry out commercial campaigns in advance of potentials start up some time in 2012. As an extra environmental step and until consent to discharge with local sewage undertaker United Utilities is in place, effluent from development runs is being tinkered off site for disposal.

The operator has provided supplementary application information (specially general information report AG060211 and H1 assessment AG060211A both updated within schedule 5) describing the changes to the current process, chemicals introduced to the process and other chemicals not utilised in new process currently utilised in existing processes. Note the finished product will still be influenza vaccine with a different trade name (AgrippalR/AflunovR). The same manufacturing platform is used for both trade names. *Agrippal*R *is* a mercury free version of the trivalent seasonal influenza vaccine currently manufactured at a sister site in Italy. AflunovR is a pandemic influenza vaccine using the same processing techniques as AgrippalR but an attenuated H5N1 avian influenza virus strain.

The current application is for no increase in production capacity but the ability to switch between current influenza vaccine production utilising mercury in the process and the new products introduced via this variation.
As such the mercury based monitoring has not been altered. However by agreement with the operator the Environment Agency accepts that if in a monthly report period emissions to sewer linked to mercury and Nonylphenol ethoxylate(NPE) for site 4 (see current permit tables S4.3 d) (site 4) for monitoring and S5.1reporting) do not take place (new process operational) no monitoring linked to these substances and related reporting is required. A foot note to this affect has been added to Table S4.3 d) (site 4).

Once the mercury free process is ceased a future variation will lead to permanent removal of these requirements.

The 5 new raw materials whilst keeping process steps and equipment the same include:
1 – Sodium Citrate. Usage 118.6 litres per batch; estimated annual usage 30,836 Litres
2 – Formaldehyde - Usage 0.6 litres per batch diluted to 1 litre; estimated annual usage 156 Litres pure material/ 260 Litres in solution.

3 – Polysorbate 80 - Usage 2 to 3 x 5 litre bags per batch; estimated annual usage 3900 Litres
4 - CTAB - Usage 25 litres per batch; estimated annual usage 6,500 Litres
5 – Barium Sulphate - Usage 5kg per batch; estimated annual usage 1300kg.

Mercury and NPE used in existing process will not be utilised in new process.

The waste streams for new process are:
a) Barium sulphate solid waste; 5 kg per batch
b) Amberlite resin solid waste containing CTAB: 1 kg per batch
c) Additional discharge to existing S7 effluent emission linked to residual CTAB and formaldehyde content - but total effluent volume per annum no higher than operating with old products.

Waste Facilities on Site 4.
Enhanced waste storage facilities, allowing separation of waste types within seven different specially designed metallic containers for containment is introduced with this variation.

Section 2 of document AG060211 provides the details but in brief the 7 waste types each with a separate container include:

- Flammable Storage Container
- Non-flammable Store
- Acid Storage Container
- Alkali Storage Container
- Toxics Storage Container
- Oxidiser Storage Container
- Walk in Chemical Storage Container
- Oxidiser Storage Container

The initial point of concern was two surface water manholes in front of the flammable and non-flammable store containers, which have now been sealed.

In conclusion the closure of site 3 will be dealt with via a separate future partial surrender.

This document provides a full risk assessment for the changes linked to this variation.

The decision document has been underpinned by a site visit to inspect the new waste containers on site 4.

Key permit changes include:

- Table S1.2 updated to include operating techniques linked to this variation application
- Modification to Table S4.1 d) air emissions monitoring linked to updated description of emission point A20
- Modification to Table S 4.3 d) effluent emission monitoring linked to limited formaldehyde emissions and updating table foot notes.
- Improvement programme Table S1.4 amended to add a specific improvement program (IP13) linked to monitoring for variation emissions to confirm actual emissions are in line with H1 assessment estimates.

2. BAT

In the main the existing indicative BAT measures have been applied to the new variation. A summary of key changes and indicative BAT measures covered are as follows:

a) Design of a new process – environmental design assessment carried out during design phases in line with indicative BAT requirements for variation facility.
b) Environmental assessment of emissions carried out to air and water utilising H1 as discussed below.
c) Waste minimisation – amberlite resin usage is being optimised to maximise adsorption efficiency. Usage levels are low at 1 kg waste per batch. Resin is replaced after each batch.
d) Process operation is fixed and in compliance with written operating procedures in line with strict quality regulatory requirements.
e) Formaldehyde environmental impact minimisation.

The schedule 5 gave the following extra points for process control, abatement review and monitoring:

- Process control – controlled fixed amount of formaldehyde is consumed via reaction with amino acids associated with virus proteins (approximately 400 ml of 600 ml per batch). Defined repeated process minimising deviations is considered BAT.
- Formaldehyde emission to air: Material to be dispensed with a fume cupboard.
- Formaldehyde emissions to water: Operator has reviewed abatement options for residual formaldehyde effluent stream. See Appendix 3 of schedule 5 response for details. These methods with comments on effectiveness are as follows:
  Existing effluent treatment technology (nano-filtration and carbon adsorption ineffective against formaldehyde) , chemical treatment e.g. sodium hypochlorite (poor removal % at low concentrations and site previous problem with chlorine gas sump build up) , biological treatment (microbiological degradation ; cost benefit versus environmental benefit limited combined with major product regulatory implications), substitution of formaldehyde with different material (alternatives are either more toxic and /or provide greater environmental impact).

The operator conclusion was to monitor formaldehyde emissions levels and perform a H1. This H1, as reviewed in detail below, concluded environmental impact is insignificant. The operator is committed to monitoring the process effluent stream to substantiate this initial assessment. We have actioned the improvement program IP13 to cover initial commissioning period monitoring and then a limited three month period of weekly sampling in order to back up this conclusion.

This is considered BAT as it is not proportionate to require extra measures with environmental impact estimated as insignificant. However the wording of the monitoring allows us to review the monitoring frequency after three months of data to follow up any concerns.

In addition the operator has confirmed that there are contingency storage facilities for effluent if monitoring shows any concern regarding elevated formaldehyde levels to sewer; this is utilising existing storage facilities within effluent treatment plant.
f) CTAB environmental impact minimisation.
The schedule 5 gave the following points on process control, abatement and monitoring plus contingency measures:

- CTAB usage minimised via careful process design (25 litres per batch of 1 % CTAB equivalent to 148 ml CTAB).
- CTAB abatement via Amberlite CTAB adsorption to maximise removal (99.5%)
- CTAB potentially contaminated stainless steel vessel – designed for efficient and consistent drainage of pre and post cleaning minimising peak CTAB releases.
- CTAB alternatives have been investigated but suitable alternatives would lead to a greater potential environmental impact.
- Removal of CTAB is a critical process parameter. The crude products are checked for presence of CTAB post amberlite treatment. If elevated concentrations of CTAB are detected further treatment within the enclosed process system.
- The cleaning step with the maximum CTAB amberlite concentration has been utilised for H1 assessment below ; as this discharge is no more than several minutes per day and total volume 140 litres the impact is actually on short term.
- Pre- commercial batches will be sampled for CTAB (5 road tankers minimum) – with data submitted to ourselves.
- Commissioning monitoring of process will be undertaken over 25 batches and a minimum of 10 effluent samples – this is covered in improvement program IP13.
- In addition the operator has confirmed that there are contingency storage facilities for effluent if monitoring shows any concern regarding elevated formaldehyde levels to sewer; this is utilising existing storage facilities within effluent treatment plant.
- Given that the H1 assessment concluded that CTAB short term process contribution is insignificant (see specific H1 to water
- assessment below) it is considered that the above measures are satisfactory to be considered indicative BAT to minimise
- environmental impact.

g) Waste storage facilities. Key features to minimise environmental impact include individual storage container labelling, inspection procedures, sump volumes above 10 % of individual internal storage container volumes and greater than 25 % of total storage container volumes, spill management for spills within metallic containers, sealing of local manholes outside metallic containers to surface water and provision of grills, sumps and spill kit to minimise impact on surface water drain approximately 5 metres away. Further details provided by the operator include a specific risk assessment and operating procedure for usage of waste storage facilities in their schedule 5 response (document reference. 11-08 RA-34).
These are reviewed in detail in section 5 of this document.
In conclusion we consider the operator has utilised indicative BAT measures to minimise environmental impact linked to this variation. The environmental emissions assessment below confirms that emissions have insignificant environmental impact providing back up to this assertion.

3. H1 to air

Basis of H1:
There are two emissions to atmosphere linked to this variation
A20 and A29 formaldehyde emissions

The A20 emission –Upstream Manufacturing vent header – emission from a fume cupboard.
Formaldehyde will be dispensed in this cupboard into 0.6 litres quantities per batch (maximum one dispensation per day).
From chemical molecular mass for formaldehyde an estimated emission of 0.24 mg/m3 was calculated for input into H1 assessment.
The A29 emission - this is a HVAC system with negligible formaldehyde emission and was not considered.

A20 emission for formaldehyde.

Parameter	Release mg/m3 Long term	Release g/s Long Term	Release mg/m3 Short term	Release g/s Short Term	Annual mass emission estimate kg
Formaldehyde	0.24	0.00012	0.24	0.00012	0.009

Note:
Basis – To establish a conservative emission, the molecular mass of formaldehyde (30.03g) was assumed to occupy a standard volume of gas (1mol occupies 24.06Lt of air at standard atmospheric temperature and pressure).
The emission input into the H1 model was therefore 0.24 mg/m3.
Annual emission based on 5 minutes per day emissions over 260 days.

H1 screening stage 1
Step 1
The emissions which are equivalent to environmental insignificant impact requiring no further modelling/assessment are:

- PC (Long term) < 1 % of the LT Environmental benchmark.

	LONG TERM					SHORT TERM		
Parameter	PC LT µG/M3	EAL/EQS µG/M3	PCLT/EAL %	PCLT > 1% of EAL	PC ST µG/M3	EAL/EQS ST µG/M3	PCST/EAL %	PC ST > 10 % of EAL
Formaldehyde	0.0105	5	0.21	No	0.259	100	0.259	No

Note:

- PC stands for Process Contribution for Installation
- This assessment is majorly conservative as in reality dispensing of formaldehyde only takes place for 5 minutes per day.

Conclusions
The formaldehyde emissions screen out in terms of long and short term impact as insignificant, even with above highly conservative assumptions. As such no further modelling and assessment is required.

4. H1 to water

A H1 screening tool assessment has been made for CTAB and formaldehyde
For formaldehyde with the presence of EQS's in our H1 annex d) guidance the operator has utilised the screening tool spreadsheet on our website. With the lack of EQS's for CTAB the operator has developed a method utilising comparison with others materials with equivalent legal doses (LD50's) and then completed a manual H1 assessment (the basis for these assessments is found in application document AG062011A).

- **Maximum effluent flow rate assumed as 315 m3/day**
- **Average effluent flow rate assumed as 300 m3/day**

The final H1 submission from the operator is that found in schedule 5 response as document AG060211B.

Formaldehyde
This assessment is based on actual 2010 monitoring data from development trials (22samples) as follows:

- Formaldehyde maximum release 5.02mg/l.
- Formaldehyde mean release 1.582mg/l

The operator H1 assessment makes no reduction for the fact that tanker concentrations were based on 60 m3 maximum batch volumes whilst daily average effluent flow rate as above is 300 m3. Hence a 5 fold concentration reduction actually applies. This reduction is included in our assessment.
As background United Utilities have given initial feedback that they are minded to set a 10-15 mg/l limit as an update to operator's consent to discharge.

CTAB
Based upon the concentration of CTAB being used is 1%, at a daily usage rate of at most 25Lts, only 148mls/248g will be made of neat CTAB. The resin is expected to remove the majority of CTAB from the product, to an efficiency of 99.53%. Therefore at most 1.16ml or 1.1656g/day of CTAB will remain un-removed and some of this may be washed from equipment into the wastewater system. This is an equivalent of 3.884 mg/m3 or 0.00388mg/l, assuming a discharge volume of 300m3/day and uniform dilution.
CTAB was a new entrant into the database, and no EQS's were available. The model has had the EQS's calculated as per methodology in AG060211A application document.
The closest fit based on LD50 data was Propetamphos with EQS's as follows (LT 0.01 µg/l and ST 0.1 µg/l). Final data for process contributions is found in updated AG026011 submission in schedule 5 response.

This estimate is considered a very conservative approach as only cleaning step emission is only 2 minutes per day – as such only the short term estimate has been carried out.

Operator H1 assessment

Parameter	EQS Annual Average µg/l	PC LT µg/l	PC/EQS %	>4% EQS	EQS MAC	PC ST µg/l	PC/EQS	>4% EQS MAC
Formaldehyde	5	0.71	14.27	Yes	50	2.38	4.76	Yes
CTAB	-	-	-	-	0.1	0.000457	0.46	No

Formaldehyde adjustment
Based on 5 fold reduction in final sewer volume the PC for formaldehyde long and short term are more accurately:

- LT – 0.142 µg/l (2.85 % of EQS LT)
- ST – 0.476 µg/l (0.95 % of EQS ST)

i.e. both below 4 % screening threshold in line with our H1 annex d) latest guidance.

Conclusions
All emissions screen out as insignificant environmental impact; no need for further modelling

5. Waste Storage

Introduction
The reason for a change is to improve waste storage containment facilities (that currently exist on site 3) plus the movement of all operations over to site 4 which will form the only remaining site for this installation in future (part of a future partial surrender) as no main process operations take place on site3.
Section 2 of AG060211 report summarises a review on BAT options for waste storage carried out by the operator.
In brief two options were reviewed

- Construction of a bunded compound with suitable segregation of waste types
- Installation of fixed storage units with dedicated uses and integral containment.

The operator conclusion was that for the relatively small volumes of waste but the wide variety of waste option 2 was more economically attractive; the operator has maintained that equal environmental benefits would result from usage of

dedicated metallic containers. In addition the limited space available for waste storage mean the more compact metallic container option is favoured.

We have required that the same standard of containment and protection must be offered utilising the metallic containers to show this option as an indicative BAT measure.

The following is a summary of application and further schedule 5 responses to substantiate operation of these waste container facilities and spillage management in the immediate vicinity.

In essence there are two risks:
a) Spillage within the metallic containers
b) Spillage particularly of higher volume IBC's during loading and unloading to/from these metallic containers.

Fuller details of control measures (labelling, appropriate metallic container materials of construction , containment volume of container sumps, spill management and operating procedures plus tertiary containment external to the metallic containers are provided in schedule 5 response to question 7.

These measures are considered satisfactory with comments as follows:

WASTE TYPE	Materials to be stored.	Total Stored Volume (Litres)	Sump Volume (Litres)	Controls for containment
Flammable Store	Storage of embrex waste and empty alcohol based disinfectant containers	2000 maximum	2100	Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining. Container is fitted with vents, lighting is intrinsically safe by design and fire detection has been installed.
Acid Store	Sulphuric acid waste in IBCs	4000 (4 x 1 m3)	1125	Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining.
Toxics Storage Container	Empty nonylphenol ethoxylate (NP9) containers. Decontaminated beta-propiolactone reagent bottles. Empty/ used reagent bottles Thiomersal (mercury)	< 10	1125	Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining.
Alkali Storage Container	Empty reagent bottles ex Sodium Hydroxide. Empty caustic containers (contaminated)	< 100	1125	Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining.
Non-flammable store	Empty oil containers general (contaminated). Waste Lubricating oil. Empty reagent bottles ex Phosphate Buffer Solution. Non-Hazardous glass waste.	<1000	2100	Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining.
Walk in Chemical Store Container	Waste laboratory chemicals	<100	1098	Wastes will be segregated and contained within individual UN approved drums as required. Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining. It is fitted with Louvre vents top and bottom fitted with flame arrestment mesh. It is fitted with lighting and fittings suitable for a Zone 1 hazardous rating area.
Oxidiser Storage Container	Oxidising compounds	< 200	1098	Any waste transfer operations will take place within the road tanker loading/offloading area. Storage unit sump volume is >25% of maximum inventory. Galvanised container sump coated with chemical resistant epoxy lining. It is fitted with Louvre vents top and bottom fitted with flame arrestment mesh.

Overview

- All sumps comply with > 110 % of individual container volume and > 25 % of total volume stored. In terms of
- Health and Safety wise the containers are suitably vented.
- Sealed drain gulleys leading to a sump (combined gulley and sump containment volume 11,000 Litres) exist in front of higher volume containers (flammable, acid and non-flammable).
- Two surface water manholes have been sealed by acid/flammable and non-flammable containers to minimise chance of discharge to surface water.
- Although the surface level falls to the sump there is a small upward incline beyond this sump further minimising spill transfer beyond this point.
- There are further manholes approximately 5 metres beyond this sump which are not sealed; however due to above secondary and tertiary containment plus the local availability of spill kits we consider the controls provide adequate protection against discharge to surface water.

The operator has gone beyond standard operating procedures for spill management and written a specific procedure for usage of these containers (see schedule 5 operating procedure 11-08 RA-34).
Procedure includes:

- Specific task risk assessment
- Workplace precautions relating to storage facility operation
- Onsite waste material/container handling.
- Container sump inspection frequency
- Spill procedure specific to this operation.

Conclusion.
We consider that the controls are satisfactory for fugitive emissions containment based on additional information provided in the schedule 5 response.

6. Improvement Program

The main emphasis of the single improvement program is to provide effluent emission monitoring to substantiate H1 assessments discussed above as follows:

Table S1.3 Improvement programme requirements

Reference	Requirement	Date
IP13	The Operator shall submit a written report to the Environment Agency on the commissioning of the new products linked to this variation. The report shall summarise the environmental performance in addition to raw material usage and waste outputs of the plant as installed against the design estimates set out in the Application EPR/BS540IK/V006. The report shall include but is not limited to: • Effluent discharge emissions to S7 of formaldehyde and CTAB (cetyltrimethylammonium bromide). Monitoring from five separate batches to be provided as a minimum and shall be via UKAS/Mcerts accredited technique. Technique for CTAB to be provided with submission. For above emissions monitoring submissions the operator shall utilise this monitoring data to update the application H1 screening assessment, having regard to the Environment Agency H1 guidance to confirm installation environmental impact conclusions within the application. If any of the conclusions lead to increased environmental impacts from the application estimates an appropriate action plan with timescales shall be provided to minimise environmental impact.	3 months after commercial production start up