Notice of variation with introductory note

Environmental Permitting (England & Wales) Regulations 2010

Novartis Vaccines and Diagnostics Limited

Gaskill Road, Speke Vaccines
Gaskill Road
Speke
Liverpool
L24 9GR

Variation application number

EPR/BS5401IK/V006

Permit number

EPR/BS5401IK

Gaskill Road, Speke Vaccines.
Permit number EPR/BS5401IK.

Introductory note

This introductory note does not form a part of the notice

The following notice gives notice of the variation of an environmental permit.

The schedules specify the changes made to the original permit.

This variation is linked to two specific changes for site 4 operation within installation boundary as follows:

- Introduction of new product (without usage of mercury) which in the main follows existing product process flow but includes addition of 5 new raw materials and removal of three materials utilised in existing process. Details including process flow highlighting new raw materials and waste streams provided in application supplementary document AG020611 section 1.
- Provision of a new waste storage area (move from site 3 previous location). The waste is produced on site 4 and hence this change minimises material movement. Details provided in section 2 of application supplementary document AG020611

The status log of a permit sets out the permitting history, including any changes to the permit reference number.

Status Log of the permit		
Detail	**Date**	**Response Date**
Application BS5401IK (EPR/BS5401IK/A001)	Duly made 29/03/06	
Response to request for further information	16/11/06	11/12/06
Permit determined BS5401IK (EPR/BS5401IK/A001)	21/12/06	
Application for Variation YP3531UV (EPR/BS5401IK/V002)	Duly Made 28/09/07	
Variation YP3531UV determined (EPR/BS5401IK/V002)	20/12/07	
Application for Variation EPR/BS5401IK/V003	Duly Made 31/12/09	
Additional Information e-mail on minor operational changes	20/01/10	
Odour Management Plan (OMP)	28/02/10	
Initial OMP amendment		03/03/10
Oxides of nitrogen A38 emission monitoring data		05/03/10
Final OMP amendment		12/03/10
A38 oxides of nitrogen monitoring plan		15/03/10
Variation Notice EPR/BS5401IK/V003 determined	09/04/10	
Application for Variation EPR/BS5401IK/V004	Duly made 13/09/10	
Application for Partial Surrender EPR/BS5401IK/S005	Duly Made 03/02/11	
Revision of site plan		15/03/11
Confirmation of cessation of site 2 development work and drainage flushed – site returned to satisfactory state		05/05/11
Partial Surrender Notice EPR/BS5401IK/S005 determined	05/05/11	

Status Log of the permit		
Detail	**Date**	**Response Date**
Application for Variation EPR/BS5401IK/V006	Duly made 15/08/11	
Schedule 5 dated 23/08/11		01/09/11
Formaldehyde monitoring technique information		02/09/11
Draft consent to discharge		21/10/11
Variation EPR/BS5401IK/V006 determined	21/10/11	

End of introductory note

Notice of variation

Environmental Permitting (England and Wales) Regulations 2010

The Environment Agency in exercise of its powers under regulation 20 of the Environmental Permitting (England and Wales) Regulations 2010 varies

Permit number
EPR/BS5401IK

issued to:
Novartis Vaccines and Diagnostics Limited ("the operator")

whose registered office is
Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR

company registration number **3970089**

to operate a regulated facility at
Gaskill Road
Speke
Liverpool
L24 9GR

to the extent set out in the schedules.

The notice shall take effect from 21/10/2011

Name	Date
Mark Jenkins	**21st October 2011**

Authorised on behalf of the Environment Agency

Schedule 1 – conditions to be deleted

None

Schedule 2 – conditions to be amended

The following conditions are amended as a result of the application made by the operator:

- Table S1.2 as referenced in condition 2.3.1 is amended by the addition of the following four rows clarifying the operating techniques related to this latest variation:

Table S1.2 Operating techniques

Description	Parts	Date Received
Report AG060211 Detailing Operating Techniques in Section 1 for the new products process and Section 2 for the new waste storage facilities	All	Duly made 15/08/11
Schedule 5 dated 23/08/11	All	01/09/11
Formaldehyde monitoring technique information.	All	02/09/11
Draft Consent to discharge related to formaldehyde for effluent discharge	All	21/10/11

- Table S 4.1 d) Point source emissions to air (Site 4) as referenced in condition 3.6.1 and 3.6.4 is amended by the modification of the following one row changing A20 source definition:

Table S4.1d (Site 4) Point source emissions to air – emission limits and monitoring requirements

Emission point ref. & location	Parameter	Source	Limit (including unit)	Reference Period	Monitoring frequency	Monitoring standard or method (1)
A20 (Point A2 Figure 3, received 03/11/05)	No parameter set	β-propiolactone /Formaldehyde Fume cabinet: Zone 1	No limit set	-	-	-

Note

(1) Permanent sampling access not required.

- Table S 4.3 d) Point source emissions to sewer (Site 4) as referenced in condition 3.6.1 and 3.6.4 is amended by the addition of one row related to formaldehyde monitoring and changes to the foot notes as follows:

Table S4.3d (Site 4) Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements

Emission point ref. & location	Parameter	Source	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S6 (Point S1 on Figure 4, received 03/11/05) to Shaw Road sewer	No parameters set	Process Effluent[1] from S7 & Surface Water run-off[2].	No limit set	-	-	-
S7 (Point S2 on Figure 4, received 03/11/05)	Formaldehyde	The discharge of process effluent[1] from sump 2.	No limit	Weekly flow proportional composite sample.	(3)	Spectrophotometric method. UKAS accredited Sample measured at 412 nm on a spectrophotometer.
S7 (Point S2 on Figure 4, received 03/11/05)	Total Mercury	The discharge of process effluent[1] from sump 2.	10μg/l	Weekly flow proportional composite sample.	Weekly (4)	Cold vapour atomic absorption technique.
S7 (Point S2 on Figure 4, received 03/11/05)	Total Mercury (μg/l)	The discharge of process effluent[1] from sump 2.	No limit set		Monthly (4)	UKAS accredited
S7 (Point S2 on Figure 4, received 03/11/05)	Nonylphenol ethoxylate (μg/l)	The discharge of process effluent[1] from sump 2.	No limit set	Weekly flow proportional composite sample.	Monthly (4)	UKAS accredited

Note 1: Excluding segregated sources of effluent potentially contaminated with mercury and nonylphenol ethoxylate and process effluent from zones 4 & 5.

Note 2: Discharge via on oil interceptor.

Note 3: Monitoring frequency weekly for 3 months of new product operation with formaldehyde usage once commissioning IP13 monitoring complete. Afterwards monitoring as agreed in writing with the Environment Agency.

Note 4: Monitoring frequency applies only when process utilising mercury and nonylphenol ethoxylate in operation.

Schedule 3 – conditions to be added

The following conditions are added as a result of the application made by the operator:

- Table S1.3 as specified in condition 2.5.1 is amended to add the following:

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

END OF NOTICE