

## Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2010

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Meril Animal Health Limited.

Pirbright Vaccine Production Facility  
Ash Road,  
Pirbright,  
Surrey,  
GU24 0NQ

Permit number  
EPR/UP3034TG

# Pirbright Vaccine Production Facility

## Permit Number EPR/UP3034TG

### Introductory note

#### **This introductory note does not form a part of the permit**

The vaccine production facility at Pirbright has been in operation for a number of years. The Environmental Permitting (England and Wales) Regulations 2010 now encompass the activities at the site.

The installation produces vaccines for animals using multistage biological processes. Effluent is heat treated prior to discharge, and duty and standby boilers are used to generate steam for process and general heating requirements.

An on-site effluent heat treatment facility has allowed independence from the historical connection to the neighbouring Institute of Animal Health (IAH) effluent treatment system.

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

#### **Status Log of the permit**

<b>Detail</b>	<b>Date</b>	<b>Comments</b>
Application EPR/UP3034TG/A0001	Duly made 08/11/10	
Additional Information Received	08/11/10	
Permit determined	20/12/11	

End of introductory note

# Permit

The Environmental Permitting (England and Wales) Regulations 2010

**Permit number**  
**EPR/UP3034TG**

The Environment Agency hereby authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2010

**Merial Animal Health Limited.** ("the operator"),

whose registered office is

**Sandringham House**  
**Harlow Business Park**  
**Harlow,**  
**Essex**  
**CM19 5TG**

company registration number 01961886

to operate an installation at

**Pirbright Vaccine Production Facility**  
**Ash Road**  
**Pirbright**  
**Surrey**  
**GU24 0NQ**

to the extent authorised by and subject to the conditions of this permit.

Name	Date
<b>PAUL BUTLER</b>	<b>20/12/2011</b>

Authorised on behalf of the Environment Agency

# Conditions

## 1 Management

### 1.1 General management

1.1.1 The operator shall manage and operate the activities:

- (a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and
- (b) using sufficient competent persons and resources.

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

### 1.2 Energy efficiency

1.2.1 The operator shall:

- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
- (b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and
- (c) take any further appropriate measures identified by a review.

### 1.3 Efficient use of raw materials

1.3.1 The operator shall:

- (a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;
- (b) maintain records of raw materials and water used in the activities;
- (c) review and record at least every four years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and
- (d) take any further appropriate measures identified by a review.

## **1.4 Avoidance, recovery and disposal of wastes produced by the activities**

- 1.4.1 The operator shall take appropriate measures to ensure that:
- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
  - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
  - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.
- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

## **2 Operations**

### **2.1 Permitted activities**

- 2.1.1 The operator is only authorised to carry out the activities specified in schedule 1 table S1.1 (the “activities”).

### **2.2 The site**

- 2.2.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan at schedule 7 to this permit.

### **2.3 Operating techniques**

- 2.3.1 (a) The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Environment Agency.
- (b) If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan specified in schedule 1, table S1.2 or otherwise required under this permit, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.

- 2.3.2 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
- (a) the nature of the process producing the waste;
  - (b) the composition of the waste;
  - (c) the handling requirements of the waste;
  - (d) the hazardous property associated with the waste, if applicable; and
  - (e) the waste code of the waste.
- 2.3.3 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.

## **3 Emissions and monitoring**

### **3.1 Emissions to water, air or land**

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1, S3.2 and S3.3.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.

### **3.2 Emissions of substances not controlled by emission limits**

- 3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.2.2 The operator shall:
- (a) if notified by the Environment Agency that the activities are giving rise to pollution, submit to the Environment Agency for approval within the period specified, an emissions management plan;
  - (b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 3.2.3 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

### **3.3 Odour**

3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable to minimise the odour.

3.3.3 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to odour, submit to the Environment Agency for approval within the period specified, an odour management plan;
- (b) implement the approved odour management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

### **3.4 Noise and vibration**

3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan to prevent or where that is not practicable to minimise the noise and vibration.

3.4.2 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan;
- (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

### **3.3 Monitoring**

3.3.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:

- (a) point source emissions specified in tables S3.1, S3.2 and S3.3;

3.3.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.

3.3.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.3.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.

3.3.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1, S3.2, S3.3 unless otherwise agreed in writing by the Environment Agency.

## 4 Information

### 4.1 Records

4.1.1 All records required to be made by this permit shall:

- (a) be legible;
- (b) be made as soon as reasonably practicable;
- (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and
- (d) be retained, unless otherwise agreed in writing by the Environment Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
  - (i) off-site environmental effects; and
  - (ii) matters which affect the condition of the land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, unless otherwise agreed in writing by the Environment Agency.

### 4.2 Reporting

4.2.1 The operator shall send all reports and notifications required by the permit to the Environment Agency using the contact details supplied in writing by the Environment Agency.

4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment Agency) each year. The report(s) shall include as a minimum:

- (a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;
- (b) the annual production /treatment data set out in schedule 4 table S4.2; and
- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.

4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

- (a) in respect of the parameters and emission points specified in schedule 4 table S4.1;
- (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4 ; and
- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

- 4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

### **4.3 Notifications**

- 4.3.1 The Environment Agency shall be notified without delay following the detection of:
- (a) any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution;
  - (b) the breach of a limit specified in the permit; or
  - (c) any significant adverse environmental effects.
- 4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
- Where the operator is a registered company:
- (a) any change in the operator's trading name, registered name or registered office address; and
  - (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
- Where the operator is a corporate body other than a registered company:
- (a) any change in the operator's name or address; and
  - (b) any steps taken with a view to the dissolution of the operator.
- 4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:
- (a) the Environment Agency shall be notified at least 14 days before making the change; and
  - (b) the notification shall contain a description of the proposed change in operation.
- 4.3.6 The Environment Agency shall be given at least 14 days notice before implementation of any part of the site closure plan.

## **4.4 Interpretation**

- 4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.
- 4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made “without delay”, in which case it may be provided by telephone.

# Schedule 1 - Operations

**Table S1.1 activities**

<b>Activity listed in Schedule 1 of the EP Regulations</b>	<b>Description of specified activity</b>	<b>Limits of specified activity</b>
S4.5 A1 (a)	Producing Animal Vaccines	From receipt of raw materials to storage of packaged products.
<b>Directly Associated Activity</b>		
Steam generation and supply	2x1524KWth gas fired boilers with provision to run on oil if gas supply disrupted.	Includes oil receipt and storage, and demineralised water plant
Waste treatment	Thermal treatment of hazardous waste	Storage and thermal treatment of hazardous waste.

**Table S1.2 Operating techniques**

<b>Description</b>	<b>Parts</b>	<b>Date Received</b>
Application	Part ii: Technical Description – processes and controls used to prevent or minimise emissions	28/05/10
Application	Part iii: Supporting Information – section A6e	28/05/10
Additional information	Information in respect to effluent heat treatment process	20/08/10
Additional information	Part ii: Technical Description	08/11/10

## **Schedule 2 - Waste types, raw materials and fuels**

There are no waste type, raw material or fuel restrictions applied in this schedule.

## Schedule 3 – Emissions and monitoring

**Table S3.1 Point source emissions to air – emission limits and monitoring requirements**

Emission point ref. & location	Parameter	Source	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 and A2 [as shown on site plan in Schedule 7]	No parameters set	Boiler Plant	No limit set	--	--	
A3 and A4	No parameters set	Emergency Generators	No limit set	--	--	
A5 – A41	No parameters set	Ventilation extracts	No limit set	--	--	

**Table S3.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements**

Emission point ref. & location	Parameter	Source	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W1	No parameters set	-	No limit set	-	-	-

**Table S3.3 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
S1 emission to Thames Water Sewage Treatment Works <sup>1</sup>	No parameters set		No limit set	-	-	-
S2 emission to IAH facility <sup>1</sup>	No parameters set		No limit set	-	-	-
S3 emission to Thames Water Sewage Treatment Works <sup>2</sup>	No parameters set		No limit set	-	-	-

<sup>1</sup> Sewer connections at time of permit issue.

<sup>2</sup> Sewer connection after on-site effluent heat treatment facility brought on-line.

## Schedule 4 - Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

**Table S4.1 Reporting of monitoring data**

Parameter	Emission or monitoring point/reference	Reporting period	Period begins
None			

**Table S4.2: Annual production/treatment**

Parameter	Units
FMD vaccine active ingredient	kg
Blue Tongue vaccine active ingredient	kg
Total product volume	litres

**Table S4.3 Performance parameters**

Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Raw material usage	Annually	kg/ litre

**Table S4.4 Reporting forms**

Media/parameter	Reporting format	Date of form
Water usage	Form water usage 1 or other form as agreed in writing by the Environment Agency	20/12/2011
Energy usage	Form energy 1 or other form as agreed in writing by the Environment Agency	20/12/2011
SAPO Licence compliance	Form performance 1 or other form as agreed in writing by the Environment Agency	20/12/2011

# Schedule 5 - Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the EP Regulations.

## Part A

Permit Number	
Name of operator	
Location of Facility	
Time and date of the detection	

<b>(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution</b>
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<b>To be notified within 24 hours of detection</b>
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Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

<b>(b) Notification requirements for the breach of a limit</b>
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<b>To be notified within 24 hours of detection unless otherwise specified below</b>
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Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	Notification period

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

**Part B - to be submitted as soon as practicable**

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the facility in the preceding 24 months.	

<b>Name*</b>	
<b>Post</b>	
<b>Signature</b>	
<b>Date</b>	

\* authorised to sign on behalf of the operator

## Schedule 6 - Interpretation

*“accident”* means an accident that may result in pollution.

*“application”* means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 5 to the EP Regulations.

*“emissions to land”* includes emissions to groundwater.

*“EP Regulations”* means The Environmental Permitting (England and Wales) Regulations SI 2010 No.675 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

*“emissions of substances not controlled by emission limits”* means emissions of substances to air, water or land from the activities, either from the emission points specified in schedule 3 or from other localised or diffuse sources, which are not controlled by an emission or background concentration limit.

*“groundwater”* means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

*“MCERTS”* means the Environment Agency’s Monitoring Certification Scheme.

*“year”* means calendar year ending 31 December.

*“authorised officer”* means any person authorised by the Environment Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

*“hazardous property”* has the meaning given in Schedule 3 of the Hazardous Waste (England and Wales) Regulations 2005 No.894 and the Hazardous Waste (Wales) Regulations 2005 No. 1806 (W.138).

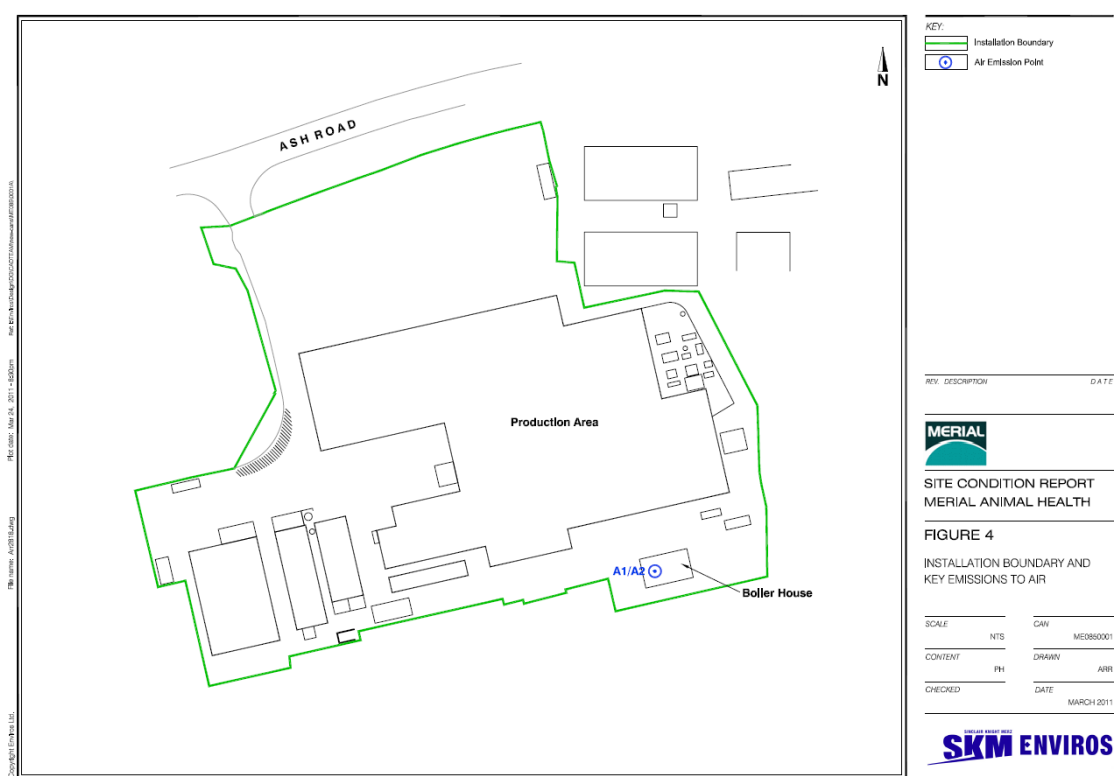
Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- (a) in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- (b) in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.

*“SAPO”* refers to a Specified Animal Pathogen Order.

# Schedule 7 – Site plan





Permit Number: UP3034TG

Operator: Merial Animal Health Limited

Facility: Pirbright Vaccine Production Facility

Form Number: [WaterUsage1 / 20/12/2011](#)

**Reporting of Water Usage for the year 2011**

Water Source	Usage (m <sup>3</sup> /year)	Specific Usage (m <sup>3</sup> /unit output)
Mains water		
<b>TOTAL WATER USAGE</b>		

Operator's comments :

Signed .....  
(authorised to sign as representative of Operator)

Date.....

Permit Number: UP3034TG

Operator: Merial Animal Health Limited

Facility: Pirbright Vaccine Production Facility

Form Number: Energy1 / 20/12/2011

**Reporting of Energy Usage for the year 2011**

Energy Source	Energy Usage		Specific Usage (MWh/unit output)
	Quantity	Primary Energy (MWh)	
Electricity *	MWh		
Natural Gas	MWh		
Gas Oil	tonnes		
TOTAL	-		

\* Conversion factor for delivered electricity to primary energy = 2.4

Operator's comments :

Signed .....  
(Authorised to sign as representative of Operator)

Date.....

Permit Number: UP3034TG

Operator: Merial Animal Health Limited

Facility: Pirbright Vaccine Production Facility

Form Number: Performance1 / 20/12/2011

**Reporting of other performance indicators for the period DD/MM/YYYY to DD/MM/YYYY**

Parameter	Units
FMD vaccine active ingredient	kg
Blue Tongue vaccine active ingredient	kg
Total product volume	litre
Raw material used (list)	kg/ litre
Full compliance with SAPO licence	Yes/ No
Date of SAPO licence audit	none
Findings of audit/ details on non-compliance	none

Operator's comments :

Signed .....  
 (Authorised to sign as representative of Operator)

Date.....