POLLUTION PREVENTION AND CONTROL ACT 1999

ENVIRONMENTAL PERMITTING (ENGLAND AND WALES) REGULATIONS 2010

PERMIT OF PROCESS

THIS IS TO CERTIFY THAT the pharmaceutical formulation and finishing processes

at: **3M Health Care Loughborough**
Derby Road, Loughborough Leicestershire LE11 0SF

National Grid Ref: SK 524 207
has been duly permitted in accordance with Regulation 13(1) of the Environmental Permitting (England and Wales) Regulations 2010 subject to the conditions outlined in this document.

Name of Operator: 3M Health Care Ltd
Registered Office 1 Morley Street, Loughborough, Leicestershire LE11 1EP

This Permit shall apply only to the installation detailed above. This Permit, consisting of twenty-three shall be subject to replacement, variation or amendment, as may be considered appropriate by Charnwood Borough Council at any time, according to provisions of Regulations, 18, 20, and 34 of the Environmental Permitting (England and Wales) Regulations 2010.

The conditions contained herein shall apply from the date of the Permit unless otherwise stated.

Signed on behalf of Charnwood Borough Council

…… Dated 12 October 2011
Beverley Green, Lead Officer- Environmental Protection
(the delegated officer for the purpose)

Counter-signed……..

Regulatory Services, Environmental Health Southfields, Southfield Road, Loughborough LE11 2TX

Introductory note

This introductory note does not form a part of the permit

The following Permit is issued under Regulation 13 of the Environmental Permitting (England and Wales) Regulations 2010 (SI 2010/675), as amended, ("the EP Regulations") to operate an installation carrying out one or more of the activities listed in Part 2 of Schedule 1 of the EP Regulations, to the extent authorised by the Permit:

Section 7 Part B
" The chemical synthesis, fermentation, extraction, formulation and finishing of pharmaceutical products and where carried out at the same site, the manufacture of intermediate products".

Status Log

Detail	*Date*	*Comments*
Deemed Application 115	Received 9/11/05	Duly made
Extension to determination granted	8/3/06	
Permit determined	10 September 2007	
Variation Notice	1 June 2009	Consolidated permit issued
Variation Notice	24 September 2010	Permission for use of dichloromethane (R40) until 31 May 2011
Variation Notice	27 May 2011	Consoldiated permit issued
Variation Notice	12 October 2011	Consoldiated permit issued

Origins of the conditions contained in the permit

The Secretary of State has issued various guidance notes to local authorities to assist with determining those conditions which represent 'best available technique' in the different circumstances which apply to each installation. The conditions within this permit have been derived from the following guidance note;

PG 6/43 (04) Formulation and Finishing of Pharmaceutical Products (as amended)

Process Description

There are four main processes that are undertaken at the installation: -

- Granulation Process
  The plant consists of mixing vessels and two calmic dryers. The calmic dryers are fluid bed driers and are fitted with bags that allow the air to circulate while containing the product. As well as the bag there are in line filters that detect any trace amount of product that may get through. There is also a detector in the line that alarms and shuts down the process if a powder leak is detected e.g. if a bag was to burst. VOC emissions are discharged to atmosphere from Calmic dryer1; no solvents are used in the production of products dried on Calmic dryer 2.

- Bead Manufacture
  The plant consists of mixing vessels and an aeromatic spray dryer. The dryer dries both beadlet and powder products. There are in line filters after the dryer to stop particles being emitted and these are equipped with differential pressure monitors that shut down the process if a pre-set pressure is breached. VOCs are discharged to atmosphere.

- Liquid Manufacturing Process
  The plant consists of bulk storage of solvent, a mixing vessel and holding tanks from which the mixture is discharged into bottles. This is a closed system.

- Meter Dose Inhalers Process
  The plant consists of mixing vessel from which Metered Dose Inhalers (MDIs) are filled. This is a closed system. All lines are equipped with extraction that then passes through a wet scrubber. The wet scrubber removes particulates before emission to atmosphere.

There are also laboratories where the products are tested. A variety of solvents are used here and fume cupboards control emissions.

VOC emissions also occur during tray drying processes. Emissions are extracted via local extract systems and leave the building through one the factory stacks (shown on drawing DIS 12087). No monitoring or control methods are currently used due to the low emissions produced.

Plant Operation

- Bulk storage of propellants – propellants are stored in pressurised bulk storage tanks shown on plan DIS 12087. These are filled by tankers using fuel hose connections. The process is computer monitored and will not allow the vessel inlet to open until a firm connection with the tanker is recognised by the system. Once the connection has been made filling takes place and the weight and pressure of the bulk storage tank

is monitored to ensure operating limits are not exceeded. During filling displaced propellant emissions from the bulk storage tank are back vented into the tanker. All storage tanks are fitted with high-level alarms. These 2 tanks are not bunded because of the volatility of contents.

- Raw Material Store – all powdered raw materials are kept on racks in the raw material store, which is inside the main manufacturing building. The active ingredients are also kept in this area but are placed in locked cages due to the nature of the chemicals. Solvents not kept in the bulk holding tanks are stored in drums in a flammable liquid store, located outside the factory in a separate building. All racks are bunded and the drums are stored on the bunded racks. Drums are checked on arrival for condition/damage and are checked on a regular basis to ensure no leaks have developed. The whole storage area is subject to contained catchment, which is emptied yearly and the waste dealt with as hazardous waste.

- Granulation Process– the required amount of solvent and solids are dispensed in to a mixing vessel. The solvent is dispensed from 205 litre drums whilst the solids are loaded via a vacuum transfer system. The mixing vessel is then sealed. The materials are then mixed and discharged in to a filter bowl prior to drying. The materials are dried in a fluid bed dryer and emissions are discharged to atmosphere. The dry mixture is then vacuum transferred into a cube hopper for tablet and capsule compression, finishing and coating. No solvents are used during the finishing process.

  The process machines and associated equipment are cleaned using non-solvent cleaning materials. Only the required amount of solvent is used in the process. Volatile organic compounds are emitted during the drying process; these are fugitive in nature and are negligible in quantity. The solvent used is methylene dichloride.

- Bead Manufacture Process – the required amount of solvent is dispensed from 205 litre drums and loaded with pre-weighed solids to a mixing vessel, which is then sealed. The materials are then mixed and discharged into a container from where they are extruded, spheronised and filtered prior to drying. The solution is sprayed onto beads in a spray dryer and the drying process commenced. VOC emissions occur during the drying process and are discharged to atmosphere; the solid particulates are filtered out. The beads are then sieved and blended prior to being put into capsules. During bead filling and capsule finishing no solvents are used.

  The process machines and associated equipment are cleaned using non-solvent cleaning materials. Only exact amounts of solvents are used in the process. There are fugitive emissions but these negligible in quantity. The main solvent being emitted is ethanol.

- Liquid Manufacture Process – solvent for this process is pumped directly from the liquid store to the process vessels, to be mixed with solids. When completed the process materials are discharged to a storage vessel from where the mixture is placed into bottles. The process is totally enclosed and the only emission is from the displacement of residual solvent saturated air in the vessel and pipe work.

  The process machines and associated equipment are cleaned using no solvents.

- Meter Dose Inhalers (MDIs) Process – Propellants and solvents for the MDIs are transferred to the concentration room for mixing. They are then filled in to the MDIs. Any escaped particulates are captured by wet-scrubbers. There are 5 wet-scrubbers, designed to take out particulates only. Wet-scrubbers 1and 3 use a pump to circulate water from the tank, over baffle plates to produce the water blanket. Air is extracted from the process LEV inlets and passes through the blanket of water where the particulates are removed before the air is discharged to atmosphere.

  The system is monitored and alarms/interlocks process when: -
  - The duct velocity is below required spec
  - Pressure differential across the water blanket is low
  - Water flow is low from the circulation pump
  - Extract fan is not running.

  The water tank is drained down to the effluent system weekly and topped up with fresh water, every month the tank and baffles are jet washed. The extract system is tested to HSG54 annually.

  Wet-scrubber 4 uses a pump to circulate water from the tank, over baffle plates to produce the water blanket. Air is extracted from the process LEV inlets and passes through the blanket of water where the particulates are removed before the air is discharged to atmosphere.

  The system is monitored and alarms/interlocks process when: -
  - The duct velocity is below required spec
  - Pressure differential across the water blanket is low
  - Water flow is low from the circulation pump
  - Extract fan is not running.

  The water from the tank is held in settle tanks, drained down to barrels and disposed of as hazardous waste every 2 weeks, at this time the baffles are jet washed. The extract system is tested to HSG54 annually.

Wet-scrubber 7 uses a rotoclone to spray water from the tank to the water blanket. Air is extracted from the process LEV inlets and passes through the blanket of water where the particulates are removed before the air is discharged to atmosphere.

The system is monitored and alarms/interlocks process when: -

- The duct velocity is below required spec
- Pressure differential across the water blanket is low
- Water flow is low from the circulation pump
- Extract fan is not running.

The water tank is drained down to the effluent system weekly and topped up with water, every month the tank is jet washed. The extract system is tested to HSG54 annually.

The equipment is cleaned using a VOC based cleaning agent, which is mainly ethanol, and the contaminated cleaning waste is collected and disposed of in closed containers. The MDIs are tested, the spray from which is extracted and passed through a wet scrubber. After testing the filled MDIs are packaged and all filling equipment is cleaned using the same VOC cleaning solution as before. This is again collected and disposed of in closed containers.

This is essentially a closed process. There are some fugitive VOC emissions, however these are negligible.

Waste

A limited amount of solid and liquid waste is stored on site in the waste compound. This area is bunded and waste is segregated into prescription only medicines/hazardous materials and solvent divided into chlorinated and non-chlorinated waste. The waste is collected by an authorised waste handler and disposed of in the appropriate manner.

Waste solvent from the clean in place system in the MDI process is pumped into a waste solvent holding tank, which is bunded. From here solvent is pumped into drums and stored in the waste compound until collected.

Unintentional Releases

Spill kits are available if drum puncture incidents occur during transportation. If spills occur in the storage area drainage culverts take the spillage to capture pits for containment. All spills

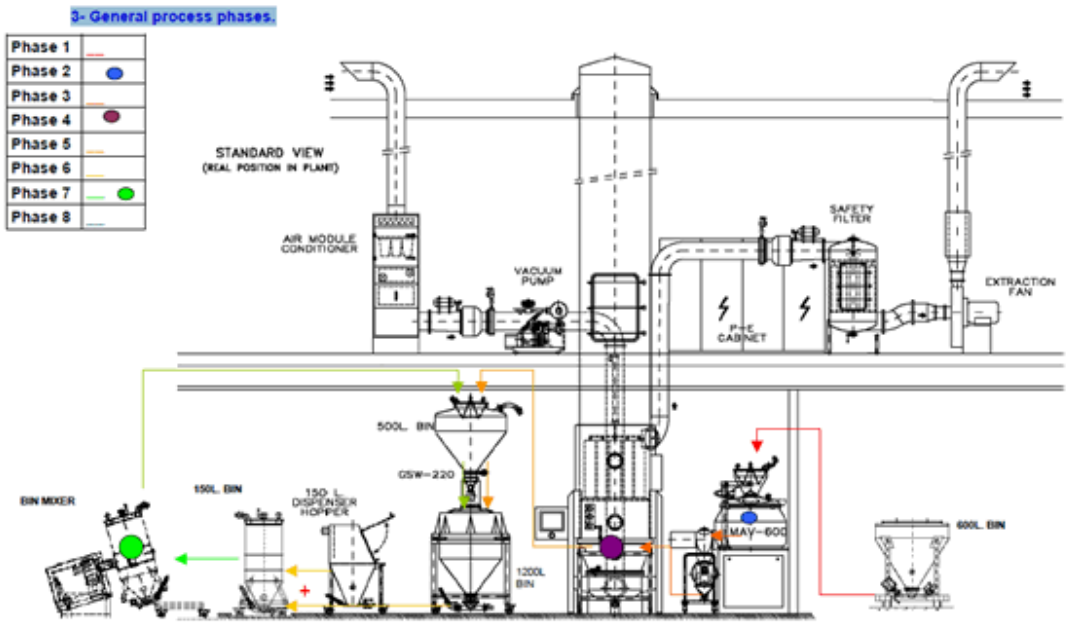
are recorded and investigated. Staff are trained in the procedure to deal with spills and the use of the spill kits themselves.

Granulation Suite Process

The granulation suite consists of individual items of equipment whose main function is to transform a paste product into a dry powder of a uniform grain size. The process is limited to the production of one product and involves loading of the high shear mixer (MAV 600) with powder and paste (this shown diagrammatically below). Once missed the product is unloaded into a conical mill (GSW 220) for milling/sieving and then loaded into a fluid bed drier for drying.

In the Fluid Bed Dryer air is drawn through the system by the Extract fan, the incoming air is filtered and heated before entering the Fluid bed dryer, the product is dried by the air and the air is filtered before leaving the dryer and passing through a safety filter (Dust Collection Unit). The filtered air is then extracted out via emission point 154.

Following drying the product undergoes further milling/sieving before mixing and homogenisation by a barrel mixer prior to loading into containers.



Solvent Emission Requirements

In order to reduce VOC emissions from the installation the company will meet the total emission limit values given in Process Guidance Note PG 6/43 (as amended).

End of Introductory Note.

The above named company is permitted to operate the activities and/or associated activities as specified in table 1 below: -

Table 1		
Activity listed in Schedule 1 of PPC Regulations/associated activity	**Description of specified activity**	**Limits of specified activity**
Section 7 Part B – formulation and finishing of pharmaceuticals carried out with a solvent consumption of 50 tonnes or more	Storage, sieving, mixing, blending, granulation, drying and pressing of pharmaceuticals, production of liquid preparations, production of aerosol preparations.	From receipt of raw materials onto the site to the dispatch of finished products and handling storage and removal of waste.

Subject to compliance with the following conditions:

Permit Conditions

Emission Limits, monitoring and other provisions

1. The following non-VOC emission limit shall apply.

Table A - Non VOC Emission Limits				
Substance	**Source**	**Emissions Limit**	**Monitoring Method – (as recommended by the Source Testing Association)**	**Monitoring Frequency**
Particulate matter	Total particulate matter from all emission points listed in table C	50 mg/Nm^3 as 15 minute mean for contained sources	In accordance with BS EN 13284-1, or equivalent, with averages taken over operating periods excluding start-up and shutdown	Annual Manual extractive testing by 31 October each year.

2. The emission limits in table B below shall be complied with.

Table B - VOC Emission Limits		
VOC in waste gases	**Total Emission Limit value**	**Monitoring**
		Unabated releases
Existing Installation	15% of solvent input	Annual Manual extractive testing from emission points listed in table C

Compliance with the Total Emission Limit Values

Compliance is achieved if the total emission from the activity expressed as a percentage of the organic solvent input to the activity is equal to or less than the total emission limit value:

Where the total emission is equal to the mass of organic solvent released in the waste gases **PLUS** the fugitive releases.

Total emission = O_1 + Fugitive

And organic solvent input is equal to the quantity of organic solvents purchased and used in the process **PLUS** the quantity of organic solvents recovered and reused as organic solvent into the process as determined as part of the Solvent Management Plan:

Organic solvent input (I) = $I_1 + I_2$

Compliance with the total emission limit value is achieved if:

$$\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100 \text{ is equal to or less than the Total emission limit value}$$

Note: The reference conditions for emission limits in this section are: 273.15°K, 101.3kPa, without correction for water vapour content, unless stated otherwise.

3. The following emission points shall be monitored to ensure compliance with the emission limits given in 1& 2 above.

Emission point reference	Source	Monitoring required	Extractive Monitoring
A3	Wet Scrubber 4	Annual Manual extractive	Annually by 31 October
A4	Wet Scrubber 3	Annual Manual extractive	Annually by 31 October
A6	Wet Scrubber 1	Annual Manual extractive	Annually by 31 October
A7	Calmic 1	Annual Manual extractive	Annually by 31 October
A8	Aeromatic	Annual Manual extractive	Annually by 31 October

A9	Wet Scrubber 7	Annual Manual extractive	Annually by 31 October

4. The introduction of dilution air to achieve the emissions concentration limits specified in condition 1 shall not be permitted.

5. No additional chimneys, vents or process exhausts which increase emissions of particulates or VOC's to atmosphere shall be provided without the written consent of Charnwood Borough Council.

Determination of Solvent Consumption

6. The operator shall determine the organic solvent consumption, the total mass of organic solvent inputs minus any solvents sent for reuse/recovery off-site, at the installation on an annual basis and this shall be submitted to Charnwood Borough Council annually by 31 January. This shall be produced in the form of a mass balance using the definitions and calculations set out in the Solvent Emission Directive (SED) Annex III and reproduced in Schedule A of this permit to determine the annual actual consumption of organic solvent.

Solvent Management Plan

7. A Solvent Management Plan (SMP) shall be produced annually by the operator and submitted to Charnwood Borough Council by 31 January. This shall be used to determine fugitive emissions from the installation and the Total Emission Limit Value required by Condition 2. The SMP shall cover the period of 1 January to 31 December of the previous year. It shall be produced using the definitions and calculations set out in Annex III of the SED and reproduced in Schedule B of this permit. The SMP shall be forwarded to Charnwood Borough Council annually and within four weeks of the end of the period to which the inventory relates. (Risk phrase solvents shall be recorded separately and not form part of this plan).

8. Total organic solvent emissions shall be calculated as described in the Solvent Management Plan referred to in Condition 7 and solvent emissions shall not exceed 15 % of the total solvent input.

Designated Materials

9. Designated materials because of their halogenated VOC content with risk phrases R40 or R68 and hazard statement H341 or H351 shall be controlled as far as is technically and economically feasible.

Other Provisions

Monitoring, investigation and recording

10. The results of all inspections, tests, monitoring (including all non-continuous monitoring and visual assessments) shall be recorded in a logbook. The log book and any continuous monitor charts or records shall be shall be kept on site and retained by the operator for a minimum of two years and made available for examination by an authorised officer of the Borough of Charnwood.

11. The operator shall provide a list of key abatement plant and shall have a written plan for dealing with its failure.

12. The Operator shall notify Charnwood Borough Council at least 7 days before any periodic monitoring exercise to determine compliance with the emission limit values. The Operator shall state the provisional time and date of monitoring, pollutants to be tested and the methods to be used.

13. The results of all non-continuous emission testing shall be forwarded to Charnwood Borough Council within 8 weeks of the completion of sampling.

14. In the event of any adverse results from any monitoring activity (both continuous and non-continuous) the Operator shall investigate as soon as the results are obtained /received. The Operator shall:
    - Identify the cause and take corrective action
    - Record (in the log book) as much detail as possible regarding the cause and extent of the problem
    - Record the remedial action taken by the Operator to rectify the situation
    - Re-test to demonstrate compliance as soon as possible and
    - Notify Charnwood Borough Council of the steps taken and the re-test results.

15. In any case where monitoring results exceed the emission limits specified in Conditions 1 and 2 above Charnwood Borough Council's Environmental Protection Service shall be notified by phone within one day of the results being obtained.

Where the emissions exceed twice the limit, Charnwood Borough Council shall be notified within 1 hour of the results being obtained.

Visible and odorous emissions

16. Emissions from any combustion processes shall in normal operation be free from visible smoke. During start up and shut down the emissions shall not exceed the equivalent of Ringelmann Shade 1, as described in British Standard BS 2742:2009.

17. All releases to air, other than condensed water vapour, shall be free from droplets and persistent visible emissions.

18. There shall be no offensive odour beyond the site boundary, as perceived by an authorised officer of Charnwood Borough Council. Where there are problems that, in the opinion of the regulator may be attributable to the installation the operator shall;

    - Inspect the process to determine which operation(s) is the cause, and

    Whilst the problems are ongoing the operator shall;

    - Ensure boundary checks are made once per day whenever the installation is in operation.
    - Make a record of the time, location and results of these checks, together with weather conditions, wind direction and wind strength.

    Once the source of the emission has been identified corrective action shall be taken by the operator to rectify the problem without delay.

Abnormal events

19. In the case of any abnormal emissions, malfunctions or breakdown leading to significant escape of particulate matter, odour or fumes occur the Operator shall:

    - Investigate and undertake corrective action **immediately**
    - Adjust the process or activity to minimise those emissions and
    - Promptly record (within one working day) the events and actions taken

20. Charnwood Borough Council shall be informed immediately by telephone where:

- the emission is likely to have an effect on the local community
- in the event of the failure of key arrestment plant, for example, bag filtration plant and scrubber units.

21. In cases where emissions are likely to cause an immediate danger to human health, the operation of the activity shall be suspended.

Calibration and Compliance Monitoring

22. Annual extractive test sampling shall meet the following requirements;

    a) For batch processes, where the production operation is completed within 2 hours, then extractive sampling shall take place over a complete cycle of the activity ; **and**
    b) The sampling period shall be sufficient such that a least 3 results are obtained.

23. For activities that are continuous or have a batch cycle that is not compatible with the time available for sampling, then the data shall be obtained over a minimum period of 2 hours in total.

24. No annual extractive testing result shall exceed the emission concentration limit specified in condition 1.

VOC abated releases

25. For periodic measurements of VOC at least three readings shall be obtained during each measurement exercise. VOC emission limit values shall be considered to be complied with if, in one monitoring exercise:

    a) The average of all readings does not exceed the emission limit values: and
    b) None of the hourly averages exceed the emission limit value by more than a factor of 1.5.

Varying of monitoring frequency

26. The frequency of particulate testing shall be increased for example, as part of commissioning of new or substantially changed activities, or where emission levels are near to or approach the emission concentration limit given above on request from a duly authorised officer of Charnwood Borough Council. The duration, methodology and extent of such monitoring shall be agreed with the Council prior to undertaking

the work. This condition shall remain suspended until such time as Charnwood Borough Council activates it by the issue of a request in writing.

Sampling Provisions

27. Relevant stacks or ducts shall be fitted with facilities for sampling which allow compliance with the sampling standards.

28. Where monitoring is not in accordance with the main procedural requirements of the relevant standard, deviations shall be reported as well as an estimation of the likely error.

Control Techniques

Non VOC Releases Control Techniques

29. Emissions of particulate matter shall be abated if necessary to meet the emission limit.

VOC and odour control – storage

30. The receipt, handling and storage of organic solvents shall be carried out so as to minimise the emission of volatile organic compounds to air.

31. Bulk storage tanks for propellants shall be light coloured.

32. Delivery connections to bulk storage tanks shall be located within a bunded area. The bunding shall be impervious, resistant to liquids and capable of holding 110% of the capacity of the largest stored container.

33. All VOC storage containers shall be stored within bunded enclosed areas, except for point of use containers. The bunding shall be impervious, resistant to liquids and capable of holding 110% of the capacity of the largest stored container

34. All fixed storage tanks shall be fitted with high-level alarms to warn of overfilling. The filling system shall be interlocked to an alarm system to prevent overfilling.

35. All raw materials with an organic solvent content shall be stored in closed storage containers.

36. Drums containing material with an organic solvent content shall be stored on bunded racking.

VOC Control – handling

37. Mixing of materials shall be undertaken in covered or enclosed mixing vessels.

38. Emissions from emptying of mixing vessels and transfer of materials shall be carried out so as to minimise emissions of volatile organic compounds, this can be achieved by use of closed transfer systems, closed mobile containers, closed containers with pipeline delivery systems and containers with close-fitting lids.

VOC Control – cleaning (including surface cleaning)

39. Cleaning operations involving organic solvents shall be periodically reviewed, normally at least once every 2 years, to identify opportunities for reducing VOC emissions (e.g. cleaning steps that can be eliminated, or alternative cleaning methods). A copy of this review shall be provided to Charnwood Borough Council within eight weeks of it being completed.

40. The dispensing of cleaning solvents shall be from a contained device or automatic system in the case of fixed manufacturing equipment or dispensed by a piston type dispenser or similar contained device, when used on wipes.

41. When organic solvent is used on wipes, pre-impregnated wipes shall be stored in an enclosed container prior to use. Where practicable no organic solvent cleaning fluids or significantly less volatile organic solvents cleaning fluids shall be used.

42. Where practical fixed equipment shall be cleaned *in situ* and such equipment shall be kept enclosed during the cleaning operation.

43. Where equipment is cleaned off-line, it should be cleaned in enclosed cleaning machines wherever possible. Enclosed cleaning systems should be sealed to prevent emissions whilst in operation, except purging at the end of the cleaning cycle. If this is not practicable, emissions should be contained and vented to suitable arrestment equipment.

VOC Control – Operational

44. A programme to monitor and record the consumption of coatings/organic solvents against product produced shall be used to minimise the amount of excess organic solvent used.

VOC Control –Waste

45. All potentially odorous and organic solvent contaminated waste materials shall be stored in closed containers.

46. Prior to disposal, empty drums and containers contaminated with organic solvent shall be closed to minimise emissions from residues and labelled so that all that handle them are aware of their content and hazardous properties.

Dust and spillage control

47. Dusty wastes shall be stored in closed containers and handled in a manner that avoids emissions.

48. Dry sweeping of dusty materials shall not be permitted. All significant deposits or spillages of particulate matter shall be removed as soon as reasonably practicable, using vacuum cleaning, wet methods, or such other suitable methods as will minimise dissemination of dust.

49. Organic solvent containment and spillage equipment shall be readily available in all organic solvent handling areas. All spillages and leaks of VOC shall be cleaned up immediately and the collected material held in an enclosed container pending removal from site.

50. A high standard of housekeeping shall be maintained.

Air Quality

Dispersion and dilution from stacks

51. Flues and ductwork shall be adequately insulated to minimise the cooling of waste gases and prevent liquid condensation on internal surface.

52. The target efflux velocity from extraction outlets to atmosphere shall be a minimum of 15 m/s under normal operating conditions (except for wet plumes).

53. Where a linear velocity of 9m/sec is exceeded in the ductwork of existing wet abatement plant, the linear velocity shall be reduced to ensure that droplet fallout does not occur.

54. Process stacks and vents shall not be fitted with any restriction at the final opening, for example, a plate, cap or cowl. All discharge points shall be vertically upwards

55. Stacks and ductwork shall be cleaned regularly to prevent the accumulation of material as part of the routine maintenance programme. Details of inspections shall be recorded in the log book and be made available for examination by an authorised officer of Charnwood Borough Council upon request.

Management

Training

56. Staff at all levels shall receive the necessary formal training and instructions in their duties relating to control of the process and emissions to air. Particular emphasis shall be given to;

- Awareness of their responsibilities under this permit in dealing with conditions likely to give rise to VOC emissions, such as in the event of spillage;
- Minimising emission on stat up and shut down
- Action to minimise emissions during abnormal conditions

57. The operator shall maintain a statement of training requirements for each operational post and keep a record of the training received by each person. These documents shall be made available for inspection to a duly authorised officer of Charnwood Borough Council on request**.**

Maintenance

58. Essential spares and consumables, particularly those subject to continual wear, shall be held on site when the supplier is not able to provide items from stock within one working day, so that spray booth breakdowns can be rectified rapidly.

59. Effective preventative maintenance shall be employed on all aspects of the process including all plant, buildings and the equipment concerned with the control of emissions to air. In particular:

- A Written maintenance, inspection and replacement programme for all aspects of the pollution control equipment shall be prepared, implemented

and maintained and it shall be made available for inspection by an authorised officer from Charnwood Borough Council on request.

- A written record of all maintenance carried out shall be made available for inspection by an authorised officer of Charnwood Borough Council on request.

Standard Conditions

60. If the operator proposes to make a change in the operation of the installation, he shall, at least 14 days before making the change, notify Charnwood Borough Council in writing. The notification must contain a description of the proposed change. In this condition 'change of operation' means a change which may affect the substances or concentration of substances being emitted to air.

61. The best available techniques shall be used to prevent or, where that is not practicable, reduce emissions from the installation which is not regulated by any other condition of this permit.

End of Conditions

Schedule A

Determination of Solvent Consumption

A determination of the organic solvent consumption, the total mass of organic solvent Inputs minus any solvents sent for reuse/recovery off-site, should be made and submitted to Charnwood Borough Council annually, preferably to coincide with the operators stocktaking requirements, in the form of a mass balance in order to determine the annual actual consumption of organic solvent (C:)

Where $C = I_1 - O_8$

I_1 Is the quantity of organic solvents, or their quantity in preparations purchased which are used as input into the process/activity.

A calculation of the purchased organic solvent Input ($\mathbf{I}_1$) to the process/activity, is carried out by recording:

(I) The mass of organic solvent contained in raw materials and preparations in the initial stock (IS) at the start of the accounting period; plus

(ii) The mass of organic solvent contained in raw materials and preparations in the purchased stock (PS) during the accounting period.

(iii) Minus the mass of organic solvent contained in raw materials and preparations in the final stock (FS) at the end of the accounting period.

Total Organic Solvent Input ($\mathbf{I}_1$) = IS + PS – FS

Schedule B

Solvent Management Plan

The definitions in Annex III of the SED are as follows and are shown diagrammatically below.

Inputs of Organic Solvent in the time frame over which the mass balance is being calculated **(I)**

I1 The quantity of organic solvents or their quantity in mixtures purchased which are used as input into the process/activity (including organic solvents used in the cleaning of equipment, but not those used for the cleaning of the products).

I2 The quantity of organic solvents or their quantity in mixtures recovered and reused as solvent input into the process/activity. (The recycled solvent is counted every time it is used to carry out the activity.)

Outputs of Organic Solvents in the time frame over which the mass balance is being calculated **(O)**

O1 Emissions in waste gases.

O2 Organic solvents lost in water, if appropriate taking into account waste water treatment when calculating O5.

O3 The quantity of organic solvents which remains as contamination or residue in products output from the process/activity.

O4 Uncaptured emissions of organic solvents to air. This includes the general ventilation of rooms, where air is released to the outside environment via windows, doors, vents and similar openings.

O5 Organic solvents and/or organic compounds lost due to chemical or physical reactions (including for example those which are destroyed, e.g. by thermal oxidation or other waste gas or waste water treatments, or captured, e.g. by adsorption, as long as they are not counted under O6, O7 or O8).

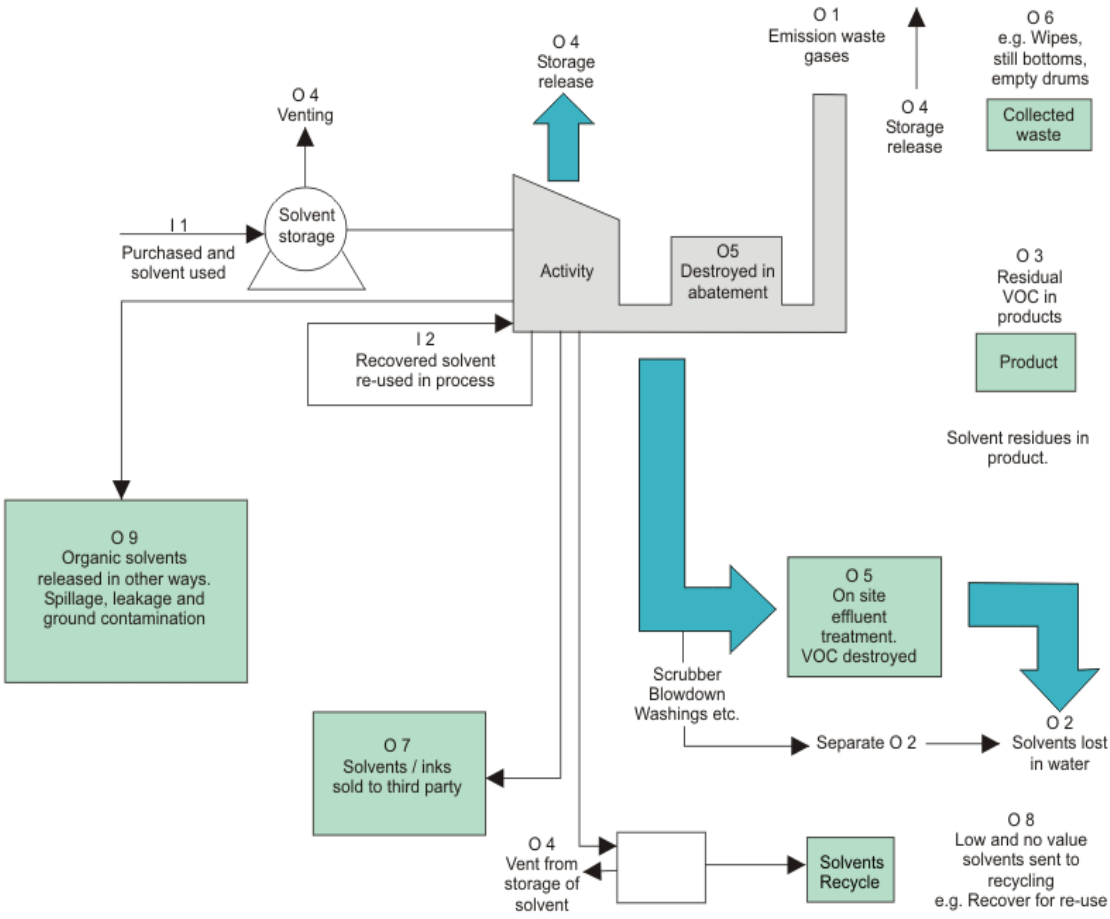
O6 Organic solvents contained in collected waste.

O7 Organic solvents, or organic solvents contained in mixtures, which are sold or are intended to be sold as a commercially valuable product.

O8 Organic solvents contained in mixtures recovered for reuse but not as input into the process/activity, as long as not counted under O7.

O9 Organic solvents released in other ways

Solvent Management Plan Inputs and Outputs



Solvent Management Plan	Solvent Emissions Directive Activities
Consumption = I 1 - O 8 Actual solvent emission = I 1 - O 5 - O 6 - O 7 - O 8 Fugitive emission (F) = I 1 - O 1 - O 5 - O 6 - O 7 - O 8 OR Fugitive emission (F) = O 2 + O 3 + O 4 + O 9	Fugitive Emission Value = $\frac{F}{I1 + I2} \times 100\%$ Total emission = O 1 + Fugitive emission (F)

Appendix 1 Site Location Plan

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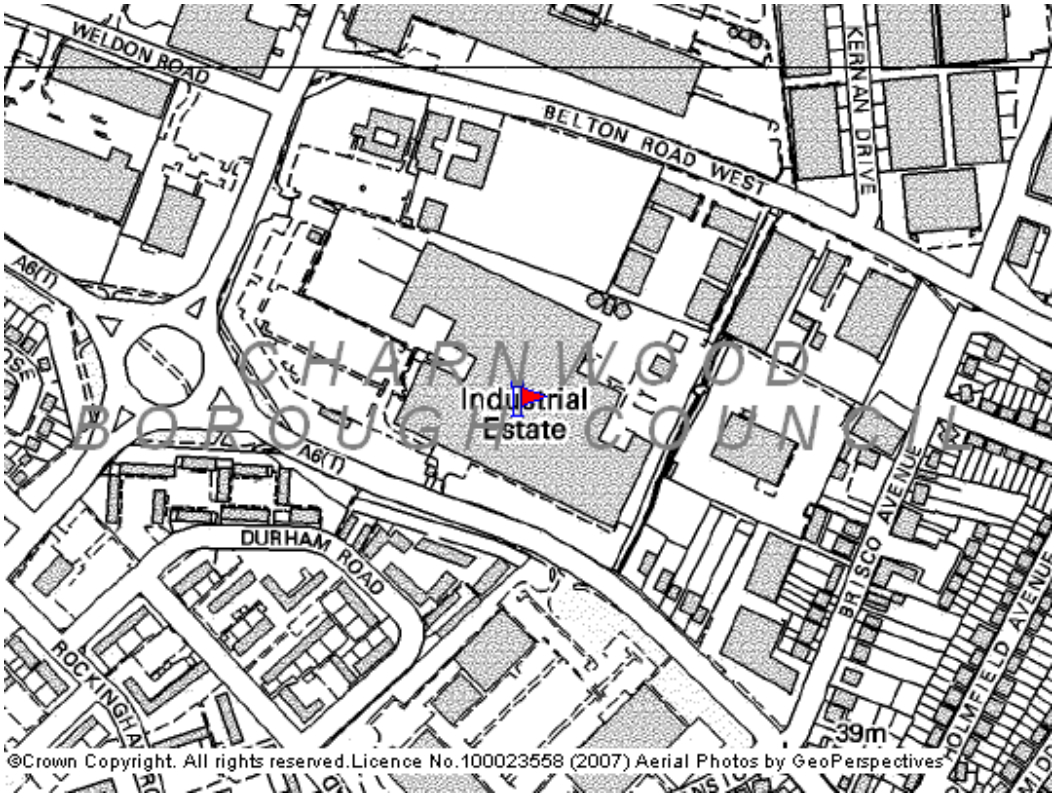
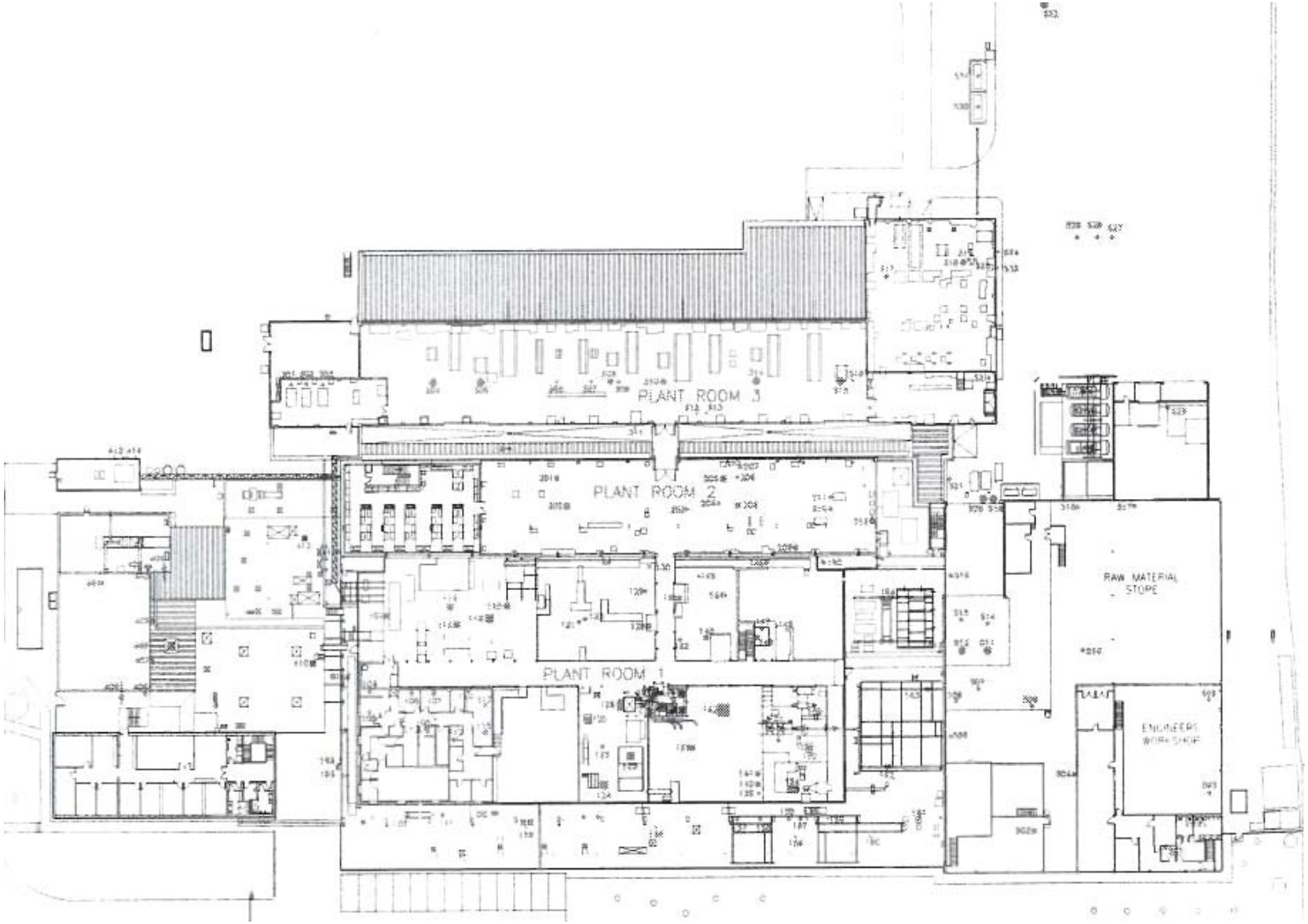


Appendix 2 Site Layout



Explanatory Notes

These notes do not comprise part of the permit but contain guidance relevant to it.

Inspections

Regular inspections will be made by officers of Charnwood Borough Council (without prior notice), in order to check and ensure full compliance with this permit.

BAT (Best Available Techniques)

The Permit includes conditions that have to be complied with. It should be noted that aspects of the operation of the installation which are not regulated by conditions of the Permit are subject to the implied condition that the Operator shall use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation. Techniques include both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned.

Health and Safety at Work and Other Statutory Requirements

The responsibility you have under legislation for Health, Safety and Welfare in the workplace remains in force. In addition, the Permit does not relieve you of your obligations to obtain planning permission, hazardous substances consent, discharge consent from the Environment Agency, Building Regulations approval, or some Waste Disposal Licences.

Submission of Information

Note that the Permit requires the submission of certain information to the Local Authority (LA). In addition, the LA has the power to seek further information at any time under Regulation 60(1) EP Regulations provided that it acts reasonably.

Public Registers

Considerable information relating to Permits including the Application is available on public registers in accordance with Requirement 46(1) EP Regulations. Certain information may be withheld from public registers where it is commercially confidential or contrary to national security.

Variations to the Permit

This Permit may be varied in the future (by the LA serving a Variation Notice on the Operator). If the Operator itself wants any of the Conditions of the Permit to be changed, it must submit a formal Application. The Status Log within the Introduction will include summary details of this Permit, variations issued up to that point in time and state whether a consolidated version of the Permit has been issued.

Surrender of the Permit

Where the Operator intends to cease the operation of an installation (in whole or in part) The LA should be informed in writing, such notification must include the information specified in Regulation 24 or Regulation 25 and Part 1 of Schedule 5 of the EP Regulations.

Transfer of the Permit or part of the Permit

Before the Permit can be wholly or partially transferred to another person, an Application to transfer the Permit has to be made jointly by the existing and proposed holders. A transfer will be allowed unless the LA considers that the proposed holder will not be the person who will have control over the operation of the installation or will not comply with the conditions of the transferred Permit.

Annual Subsistence Fee

In accordance with Regulation 65(1) of the EPR Regulations the holder of a permit is required to pay a fee for the subsistence of the permit. This fee is payable annually on 1st April. You are advised that under the provisions of Regulation 22 of the EPR Regulations, if you fail to pay the fee due promptly, Charnwood Borough Council may revoke the permit. You will be contacted separately each year in respect to this payment.

Talking to us

Please quote the Permit Number if you contact Charnwood Borough Council about this Permit. To give a Notification under Conditions 16 and 21 the Operator should use the telephone number 01509 634636 or any other number notified in writing to the Operator by Charnwood Borough Council for that purpose.

Appeals in relational to Environmental Permits

1. Anyone who is aggrieved by the conditions attached to a Permit can appeal to the Secretary of State for the Environment, Food and Rural Affairs within 6 months from the date of the permit issue.

2. Appeals must be made in accordance with the requirements of Regulation 31 and Schedule 6 of the EP Regulations and should be addressed as follows:

   The Planning Inspectorate
   Environment Team, Major and Specialist Casework
   Room 4/04 Kite Wing
   Temple Quay House,
   2 The Square,
   Temple Quay,
   Bristol, BS1 6PN

3. An appeal bought under Regulation 31(b) in relation to the conditions in a permit will not suspend the effect of the conditions appealed against: the conditions must still be complied with.

4. There are no forms or charges for appealing. However for an appeal to be valid, appellants are legally required to provide information as detailed in paragraphs 2(1) and (2) of Schedule 6 of the EP Regulations., namely:

   I. A statement of the grounds of appeal
   II. A copy of any relevant permit
   III. A copy of any relevant correspondence between the appellant and the regulator
   IV. A statement indicating whether the appellant wishes the appeal to be in the form of a hearing or dealt with by way of written representations.

5. In determining an appeal against one or more conditions, the Act allows the Secretary of Sate in addition to quash any of the other conditions not subject to the appeal, to direct the local authority either to vary any of these other conditions or to add new conditions.