



CHARNWOOD BOROUGH COUNCIL

**POLLUTION PREVENTION AND CONTROL ACT 1999
ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)
REGULATIONS 2016**

PERMIT REF. NO. 155

Charnwood Borough Council hereby permits, under regulation 13 of the of the Environmental Permitting (England and Wales) Regulations 2016

Kindeva Drug Delivery Limited

whose registered office is:

Derby Road, Loughborough, Leicestershire LE11 5SF

To operate a pharmaceutical formulation and finishing activity at:

Kindeva Drug Delivery Limited

Derby Road, Loughborough, Leicestershire LE11 5SF

subject to the conditions outlined in this document. The conditions contained herein shall apply from the date of the Permit unless otherwise stated.

Name	Date
Beverley Green	18 June 2020

Authorised on behalf of Charnwood Borough Council

Permit issued by:

Regulatory Services, Environmental Protection Southfields, Southfields Road,
Loughborough, Leicestershire 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 2016 (SI 2016/1154), 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:

“The formulation and finishing of pharmaceutical products with solvent consumption >50 tonnes”.

Status Log

The status log of the permit sets out the permitting history, including any variations issued.

Detail	Date	Comments
Partial Transfer Application of permit 115	30 April 2020	Duly made
New Permit determined	18 June 2020	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 conditions. The conditions within this permit have been derived from the following guidance note;

PG 6/43 (11) Formulation and Finishing of Pharmaceutical Products

Process Description

The main activities undertaken at the installation include:

1. Raw Material Storage
2. Inhalation Processes
3. Packing of Preparations
4. Waste / Effluent

1. Raw Material Storage

- Bulk storage of propellants – propellants are stored in pressurised bulk storage tanks. These are filled by tankers using fuel hose connections. 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.

- Bulk storage of solvents – Solvents are stored in 200 litre drums on two tier racking within a large external, naturally well-ventilated structure. There is a solvent sampling booth located in this structure the purpose of which is to test solvent prior to acceptance for manufacture. All racks are bunded.
- Raw Materials – all powdered raw materials are stored internally within the Raw Material Store, these materials are kept on racks. Active ingredients are also kept in this area but are placed in locked cages due to the nature of the chemicals. There are over >100 different raw materials stored on site in varying quantities (g to kg).

All deliveries are supervised by competent and trained employees.

Bulk Tank Storage

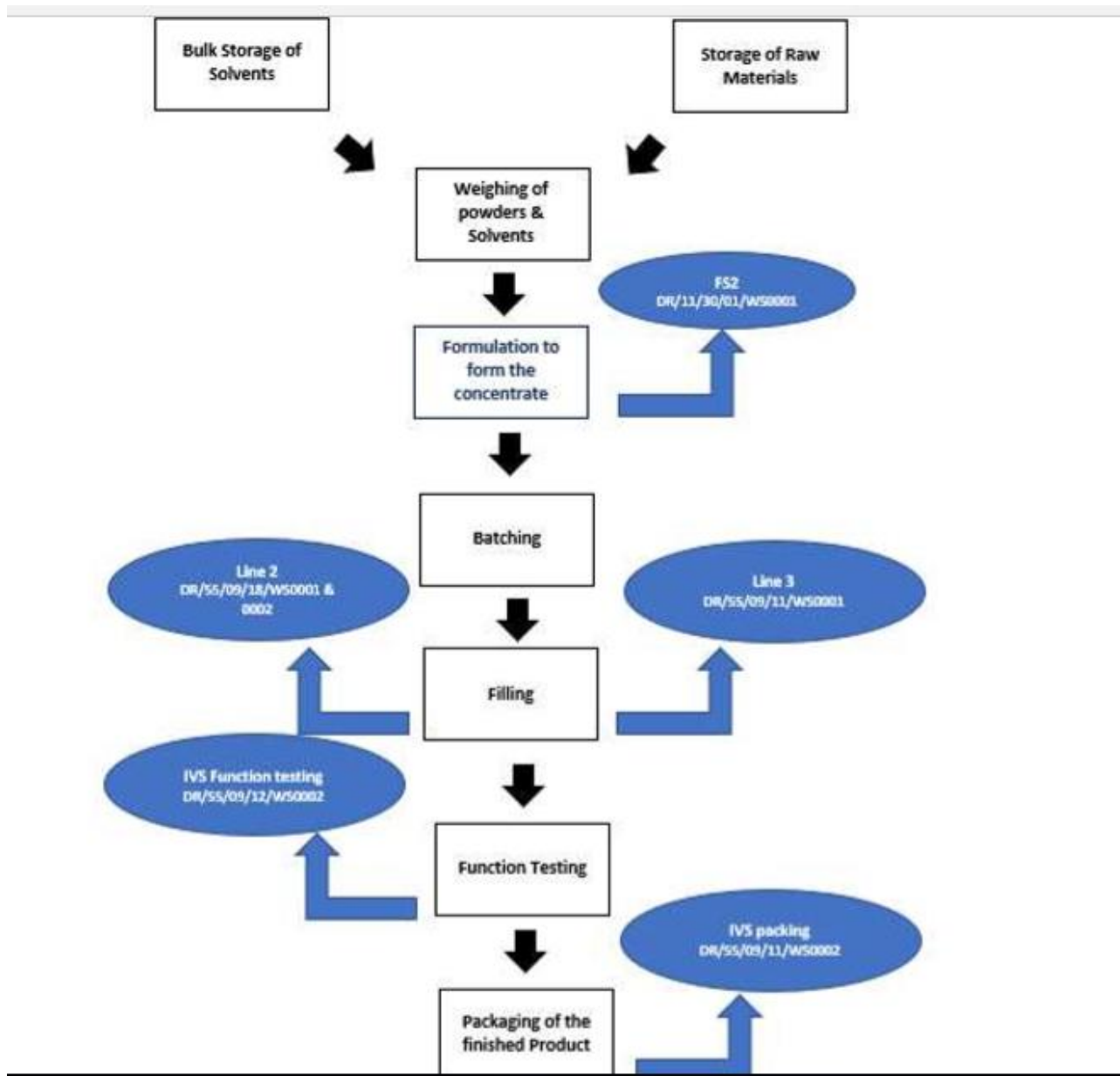
Tank Identification (Name)	Tank Purpose (Storage or Secondary Containment)	Installation Date of Tank	Construction Material of Tank	Tank Capacity	Containment
Effluent Tank DR/55/14/01	Effluent settlement	1994	Steel	87000 L	Bunded
Effluent Tank DR/55/14/01	Effluent settlement	1994	Steel	13890 L	Bunded
Waste Ethanol (DR/55/15/01)	Storage	2017	Steel	18000 L	Bunded
Nitrogen (DR/55/03/01)	Storage	1986	Steel	55900 Kg	Not Required
Propellant 227 (DR/55/05/07)	Storage	2013	Stainless steel	2800 Kg	Not Required
Propellant 134A (DR/11/05/01)	Storage	2013	Stainless steel	2800 Kg	Not Required

2. Inhalation Processes:

This process comprises the following steps:

- Dispensing / weighing
- Mixing
- Filling
- Function Testing

Process flow- Inhalation Process



Dispensing / weighing

Active pharmaceutical ingredients are weighed within an isolator and transferred to a cold concentrate vessel where they are mixed to form the product concentrate.

Mixing

The concentrate is mixed with chilled propellant within a large batching vessel.

Filling

This batching vessel inks directly by pipework to the product filling process and Metered Dose Inhalers (MDIs) are prepared by cold filling empty aerosol cans with the active pharmaceutical ingredient, solvent (ethanol) and propellant.

A metered valve is added to each can and crimped into place at the point of fill. The filled cans are conveyer transferred from the filling enclosure where they are check-weighted for correct fill weight. At this point the cans can be rejected into a ventilated bin if fill weight is not within defined product limits. The filled cans are then leak tested in a water bath, leaking cans are rejected at this point in the process.

Function Testing

The filled aerosol units are function tested to check the valve function to make sure that it delivers the correct dose of product.

Inhalation Process- Emissions

Inhalation Process Environmental Controls:

1. The fillhead is extracted to wet scrubber
2. The ventilated bin is extracted to wet scrubber
3. The waterbath is extracted to wet scrubber
4. The function tester / packaging line is extracted to wet scrubber

3. Packing of Preparations

Packaging of the finished products may include the printing of labels, the packaging of products into patient packs and boxing into shippers. These operations may give rise to small releases of VOC and dust which are handled via the wet scrubber abatement system.

4. Waste/Effluent

Waste is stored on site within the site waste compound. Formal waste management procedures are in place with trained and competent waste coordinator overseeing activities. This area is located away from the main site buildings on the site perimeter and is bunded – see layout below for site location..

Process waste-water (washings) is directed into the on-site effluent settling plant (located adjacent to the waste compound) which is discharged under consent from Severn Trent Water Limited.

The waste is segregated into prescription only medicines / hazardous materials and general waste and solvent. The solvent waste is segregated into chlorinated and non-chlorinated waste. The waste compound is padlocked secured with restricted access.

All waste is collected by an authorised waste handler and disposed of off-site.

End of Introductory Note.

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

Activity	Description of specified activity	Limits of specified activity
Formulation and finishing of pharmaceuticals carried out with a solvent consumption of 50 tonnes or more.	Storage, mixing, filling, function testing, 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. The installation boundary and key emission points mentioned in permit conditions are shown in the Appendix 1 attached to this permit.

Subject to compliance with the following conditions:

Permit Conditions

Emission Limits, monitoring and other provisions

1. The non-VOC emission limits, methods and frequency of monitoring set out in Table 2 shall be complied with.

Substance	Source	Emission Limit	Monitoring Method – (as recommended by the Source Testing Association)	Monitoring Frequency
Particulate matter	All emission points listed in Table 4 below	50 mg/Nm ³ as 15 minute mean for contained sources	Manual extractive testing in accordance with BS EN 13284-1, or equivalent, with averages taken over operating periods excluding start-up and shutdown	By 30 April 2021 and then biennially
<p>Notes:</p> <ol style="list-style-type: none"> 1.All periodic monitoring results shall be checked by the operator on receipt and sent to the Council within 8 weeks of completion of sampling. 2.The reference conditions for limits are: 273.1K, 101.3kPa, without correction for water vapour content, unless stated otherwise. 3.All periodic monitoring shall be representative, and shall use standard methods. 4.The emission limits do not apply during start-up and shut down. All emissions shall be kept to a minimum during these periods. 5. Compliance by dilution is not permitted. 				

2. The VOC total emission limit value, calculation methods and monitoring, set out in Table 3 shall be complied with.

Table 3– Total Emission Limit			
VOC in waste gases	Total Emission Limit value/requirement	Total Emission	
		Fugitive releases	Contained releases
Existing Installations	15% of solvent input	Determined in accordance with Schedule A to this permit.	Determined from continuous monitoring and recording
<p>Compliance is achieved if: the total emission from the activity expressed as a percentage of the organic solvent input into the activity is equal to or less than the total emission limit value:</p> <p>Where the total emission is equal to the mass of organic solvent released in the waste gases PLUS the fugitive releases.</p> <p>Total Emission = O₁ + Fugitive</p> <p>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 re-used as determined as part of the solvent management plan.</p> <p>$\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100$ is equal to or less than the total emission limit value</p> <p>NOTE the fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container</p>			

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

Table 4 – Emission Monitoring Points					
Ref	Emission Ref.	System Number	Application	Location	Monitoring
Wet Scrubbers					
01	IVS Line 3	DR/55/09/11/WS0001	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
02	IVS packing	DR/55/09/11/WS0002	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
03	Function Testers	DR/55/09/12/ WS002	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
04	IVS Line 2	DR/55/09/18/WS001	Wet Scrubber	Plant Room 1 DR1.075	Manual extractive
05	IVS Line 2	DR/55/09/18/WS002	Wet Scrubber	Plant Room 1 DR1.075	Manual extractive
06	Formulation Suite	DR/11/30/01/WS001	Wet Scrubber	External Boiler House Annex DRG.287	Manual extractive

Determination of Solvent Consumption

4. The operator shall determine the actual consumption of organic solvent (the total mass of organic solvent inputs minus any solvents sent for reuse/recovery off-site), at the installation on an annual basis. This shall be produced in the form of a mass balance and submitted to Charnwood Borough Council annually by 31 January.

$$\text{Where } C = I_1 - O_8$$

Note: Further details on determining Solvent Consumption can be found in Schedule A of this permit.

Solvent Management Plan

5. 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 demonstrate compliance with 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.

Further details on the definitions and calculations required are set out in Schedule A of this permit.

Designated Materials

6. Designated materials because of their halogenated VOC content with hazard statements H341 or H351 shall be controlled under contained conditions as far as is technically and economically feasible.

Monitoring, investigation and recording

7. The operator shall keep written or computer records of all inspections, tests and emission monitoring, (including all non-continuous monitoring and visual assessments) of the permitted activity. Records shall be kept on site and retained by the operator for a minimum of two years.
8. Corrective action shall be taken immediately if any periodic monitoring result exceeds a limit in Table 2. Monitoring shall be undertaken or repeated as soon as possible thereafter and a brief record shall be kept of the main actions taken.

Abnormal events

9. In the case of abnormal emissions, malfunction or breakdown leading to a significant escape of particulate matter, odour, fume or visible airborne emission, the operator:
 - Investigate and take remedial action immediately;
 - Adjust the process or activity to minimise those emissions; **and**
 - Promptly record the events and actions taken.
 - The record of events shall be available to an authorised officer of Charnwood Borough Council on request.
10. Any emission likely to have an effect on the local community or failure of key arrestment plant (for example, bag filtration plant and scrubber units) shall be notified to Charnwood Borough Council without delay by telephone.
11. In cases where non-compliance is likely to cause an immediate danger to human health or threatens to cause an immediate significant adverse effect upon the environment, the operation of the activity must be suspended.

Standard Conditions

12. 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.

End of Conditions

Schedule A (reproduced from Process Guidance Note 6/43(11))
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 = O₁ + 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) = I₁ + I₂

Compliance with the total emission limit value is achieved if:

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

A determination of the organic solvent consumption is the total mass of organic solvent Inputs minus any solvents sent for reuse/recovery off-site. This should be in the form of a mass balance in order to determine the annual actual consumption of organic solvent (C:)

Where $C = I_1 - O_8$

The industrial emissions Directive provides guidance on what constitutes a solvent input and output. The definitions in Annex VII, Part 7 of the industrial emissions Directive are as follows:

I₁ Is 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).

A calculation of the purchased organic solvent Input (I₁) 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 (I₁) = IS + PS – FS

O₈ Is the quantity of organic solvents contained in mixtures recovered for reuse.

Solvent Management Plan

The definitions in Annex VII, Part 7 of the industrial emissions Directive are as follows and are shown diagrammatically below.

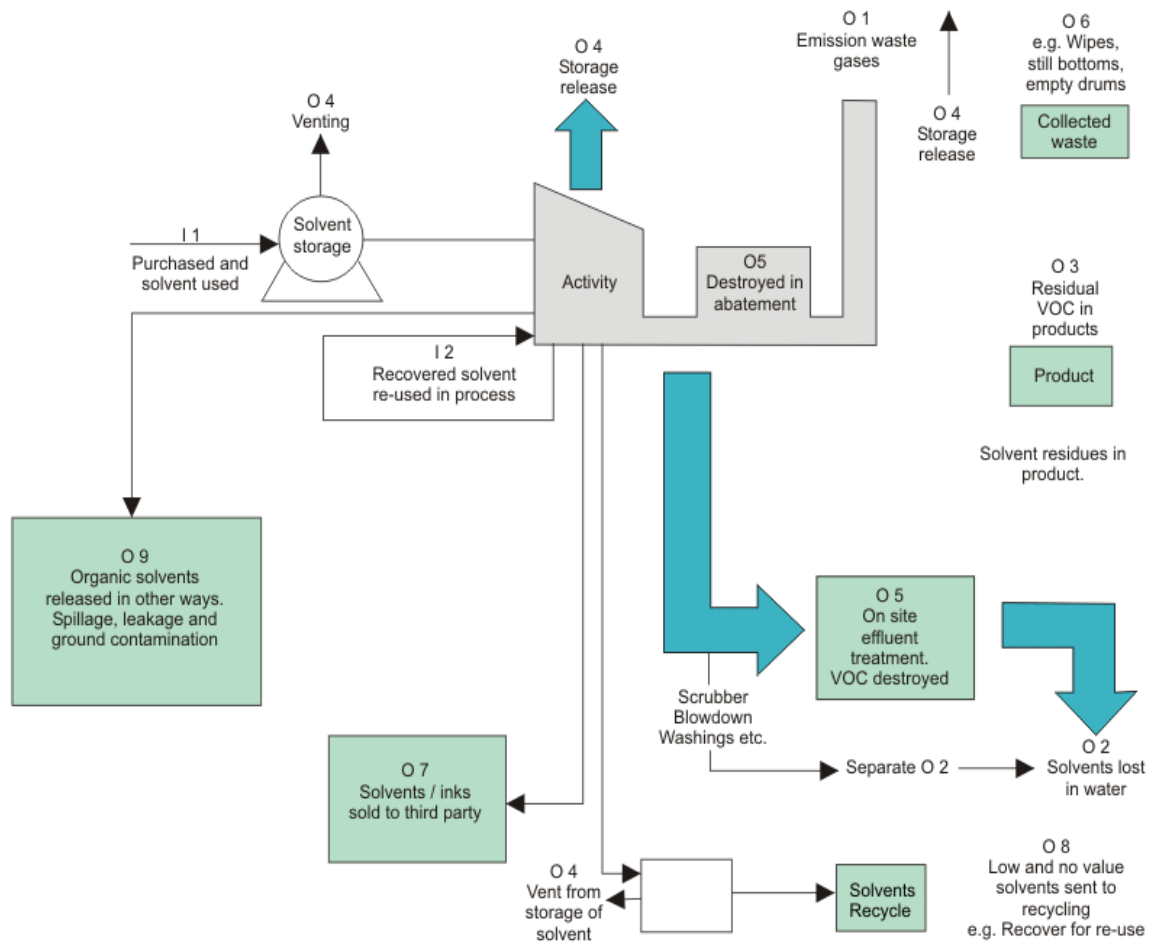
Inputs of Organic Solvent in the time frame over which the mass balance is being calculated **(I)**

- 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.

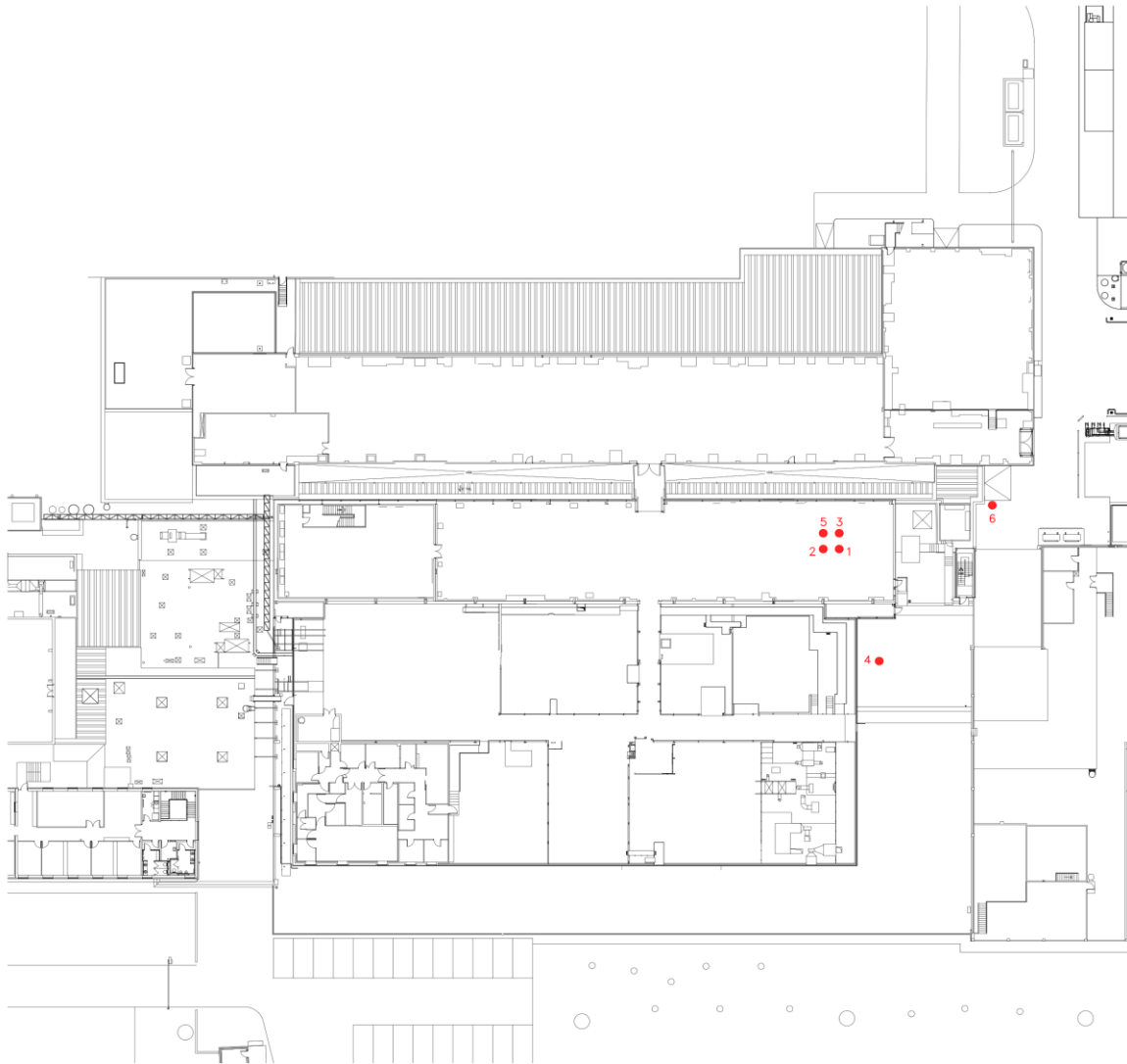
Solvent Management Plan Inputs and Outputs



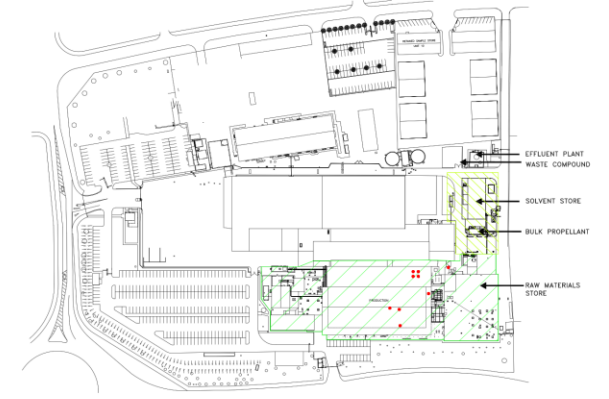
<p>Solvent Management Plan</p> <p>Consumption = I 1 - O 8 Actual solvent emission = I 1 - O 5 - O 6 - O 7 - O 8 Fugitive emission (F) = I 1 - O 1 - O 5 - O 6 - O 7 - O 8 OR Fugitive emission (F) = O 2 + O 3 + O 4 + O 9</p>	<p>Solvent Emissions Directive Activities Fugitive Emission Value =</p> $\frac{F}{I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

Site Location and Emission Points



REF	EMISSIONS REF	SYSTEM REF	APPLICATION	LOCATION
1	IVS: LINE 3	DR/55/09/11/WS0001	WET SCRUBBER	PLANT ROOM 2 DR1.073
2	IVS: PACKAGING	DR/55/09/11/WS0002	WET SCRUBBER	PLANT ROOM 2 DR1.073
3	IVS: FUNCTION TESTERS	DR/55/09/12/WS0002	WET SCRUBBER	PLANT ROOM 2 DR1.073
4	IVS: LINE 2	DR/55/09/18/WS0001	WET SCRUBBER	PLANT ROOM 1 DR1.075
5	IVS: LINE 2	DR/55/09/18/WS0002	WET SCRUBBER	PLANT ROOM 1 DR1.075
6	IVS: FORMULATION SUITE 2	DR/11/30/01/WS0001	WET SCRUBBER	EXTERNAL BOILER HOUSE ANNEX DRG.287



Segregated secure raw materials and waste storage compounds located in areas of the site with agreed common routeways accessible to both Kindeva Drug Delivery and 3M personnel.

REV. NO.	REV. DATE	DESCRIPTION	BY	CHECKED

TITLE: KINDEVA PROJECT: KINDEVA DRUG DELIVERY LTD EXHAUST/EMISSIONS POINTS IVS LOCATIONS DRAWN: [Name] CHECKED: [Name] DATE: [Date]	ALL DIMENSIONS IN MILLIMETRES. TOLERANCES: U.S.S. MACHINED - 0.150 CAST/FABRICATED - 0.150 REMOVE ALL SHARP CORNERS 0.5 x 0.5 U.S.S.	THIRD ANGLE PROJECTION DO NOT SCALE IF IN DOUBT - ASK. PROJECT NO: DIS12424
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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.

Change in Operation of the Installation

If you, the operator proposes to make a change in operation of the installation you must 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 operation. It is not necessary to make such a notification if an application to vary this permit has been made and the application contains a description of the proposed change. A 'change in operation' means a change in the nature or functioning, or an extension, of the installation, which may have consequences for the environment.

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 the 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 the EP Regulations. Certain information may be withheld from public registers where it is commercially confidential or contrary to national security. The onus is on the Operator to provide a clear justification for each item to be kept from the register. Applications for information to be excluded from the Public Register on grounds of National Security should be made to the Secretary of State.

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 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

Under the EP 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 the EP 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 contact Charnwood Borough Council please use the telephone number 01509 634636 or any other number notified in writing to the Operator by Charnwood Borough Council for that purpose.

Right To Appeal

Anyone who is aggrieved by the conditions attached to a Permit can appeal to the Secretary of State. Appeals must be sent within 6 months from the date of the permit (normally the date on the bottom of the permit).

Appeals 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

An appeal will not suspend the effect of the conditions appealed against; the conditions must still be complied with.

There are no forms or charges for appealing. However for an appeal to be valid, appellants are legally required to provide information detailed below:

- 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.

At the same time, the notice of appeal and documents (i) and (iv) must be sent to the Council.

In determining an appeal against one or more conditions, the Regulations allow the Inspector or Secretary of State to affirm or quash conditions or to add new conditions.

You will be liable for prosecution if you fail to comply with the conditions of this permit. If found guilty, the maximum penalty for each offence if prosecuted in a magistrates Court is an unlimited fine and/or 12 months imprisonment. In a Crown Court it is an unlimited fine and/or a 5 years imprisonment.

Our enforcement of your permit will be in accordance with the Regulator's Compliance Code.