



**CHARNWOOD BOROUGH COUNCIL  
ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)  
REGULATIONS 2016, REGULATION 18**

**PERMIT REFERENCE NO: 155**

**VARIATION NOTICE**

To: **Kindeva Drug Delivery Limited**

Registered Office: **Derby Road, Loughborough, Leicestershire LE11 5SF**

Charnwood Borough Council ('The Council'), in exercise of the powers conferred upon it by Regulation 18 of the Environmental Permitting (England and Wales) Regulations 2016 ("the 2016 Regulations") hereby gives you notice as follows:-

The Council has decided to vary and consolidate the conditions of Permit Reference 155 granted under regulation 13 (1) of the 2016 Regulations in respect of pharmaceutical formulation and finishing activities.

Operated by: **Kindeva Drug Delivery Limited**

At: **Derby Road, Loughborough, Leicestershire LE11 5SF**

Unless otherwise stated, the variations made by this Notice will come into effect immediately.

A consolidated permit as varied by this notice is set out in Schedule 1 attached.

Name	Date
Beverley Green	19 September 2023

Authorised on behalf of Charnwood Borough Council

Issued by:  
Regulatory Services, Environmental Protection Southfields, Southfields Road, Loughborough,  
Leicestershire LE11 2TX

## EXPLANATORY NOTES

### Notes

This notice varies the terms of the permit specified in the Notice by amending or deleting certain existing conditions and/or adding new conditions. The Schedule attached to the notice explain which conditions have been amended, added or deleted and the dates on which these have effect.

The Council have included a 'consolidated permit', which takes into account these and previous variations.

### Appeals

Under regulation 31 and Schedule 6 of the 2016 Regulations operators have the right of appeal against the conditions attached to their permit by a variation notice. The right to appeal does not apply in circumstances where the notice implements a direction of the Secretary of State/Welsh Ministers given under regulations 61 or 62 or a direction when determining an appeal.

Appeals against a Variation Notice do not have the effect of suspending the operation of the Notice. Appeals do not have the effect of suspending permit conditions, or any of the mentioned notices.

Notice of appeal against a Variation Notice must be given within **two months** of the date of the variation notification, which is the subject matter of the appeal. The Secretary of State/Welsh Ministers may in a particular case allow notice of appeal to be given after the expiry of this period, but would only do so in the most compelling circumstances.

### How to appeal

There are no forms or charges for appealing. However, for an appeal to be valid, appellants (the person/operator making the appeal) are legally required to provide the Secretary of State or Welsh Minister with the following (see paragraphs 2(1) and (2) of Schedule 6 of the 2016 Regulations):

- written notice of the appeal
- a statement of the grounds of appeal;
- a copy of any relevant application;
- a copy of any relevant environmental permit;
- a copy of any relevant correspondence between the appellant and the regulator;
- a copy of any decision or notice which is the subject matter of the appeal; and
- 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.

Appellants should state whether any of the information enclosed with the appeal has been the subject of a successful application for confidentiality under regulation 48 of the 2016 Regulations, and provide relevant details – see below. Unless such information is provided all documents submitted will be open to inspection.

### Where to send your appeal documents

Appeals should be despatched on the day they are dated, and addressed to:

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

If an appeal is made, the main parties will be kept informed about the next steps, and will also normally be provided with additional copies of each other's representations.

To withdraw an appeal – which may be done at any time - the appellant must notify the Planning Inspectorate in writing and copy the notification to the local authority who must in turn notify anyone with an interest in the appeal.

## **Costs**

The operator and local authority will normally be expected to pay their own expenses during an appeal. Where a hearing or inquiry is held as part of the appeal process, by virtue of paragraph 5(6) of Schedule 6, either the appellant or the authority can apply for costs. Applications for costs are normally heard towards the end of the proceedings and will only be allowed if the party claiming them can show that the other side behaved unreasonably and put them to unnecessary expense. There is no provision for costs to be awarded where appeals are dealt with by written representatives.

## **Confidentiality**

An operator may request certain information to remain confidential, i.e. not be placed on the public register. The operator must request the exclusion from the public register of confidential information at the time of supply of the information requested by this notice or any other notice. The operator should provide clear justification for each item wishing to be kept from the register. The onus is on the operator to provide a clear justification for each item to be kept from the register. It will not simply be sufficient to say that the process is a trade secret.

## **National Security**

Information may be excluded from the public register on the grounds of National Security. If it is considered that the inclusion of information on a public register is contrary to the interests of national security, the operator may apply to the Secretary of State/Welsh Ministers, specifying the information and indicating the apparent nature of risk to national security. The operator must inform the local authority of such an application, who will not include the information on the public register until the Secretary of State/Welsh Ministers has decided the matter.

## **Advice**

If you do not understand the contents of this notice or would like to know more about it please contact the local authority. If you would like to receive independent advice about the contents of this notice, your rights and obligations then please contact a solicitor.

## **Warning**

Failure to comply with a Variation Notice is an offence under regulation 38(2) of the 2016 Regulations. A person guilty of an offence under this regulation could be liable to (i) a fine or imprisonment for a term not exceeding 12 months or both; or (ii) to a fine or imprisonment for a term not exceeding 5 years or both, depending on whether the matter is dealt with in the Magistrates or Crown Court.

## **Data Protection**

For information about how & why we may process your personal data, your data protection rights or how to contact our data protection officer, please view our Privacy Notice [www.charnwood.gov.uk/pages/privacynotice](http://www.charnwood.gov.uk/pages/privacynotice)



**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**

Registered office:

**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	19 September 2023

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
Inclusion of bulk ethanol tank farm	16 December 2021	Variation Issued
Amended site plan	13 March 2023	Variation Issued
Additional wet scrubber added to Table 4	07 July 2023	Variation Issued
Updated site layout plan	22 August 2023	Variation Issued
Emission reference points updated	19 September 2023	Variation 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.
- Bulk storage of Ethanol- Pharmaceutical grade ethanol used in manufacturing and equipment cleaning activities. Stored externally within the bunded tank farm.
- 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.

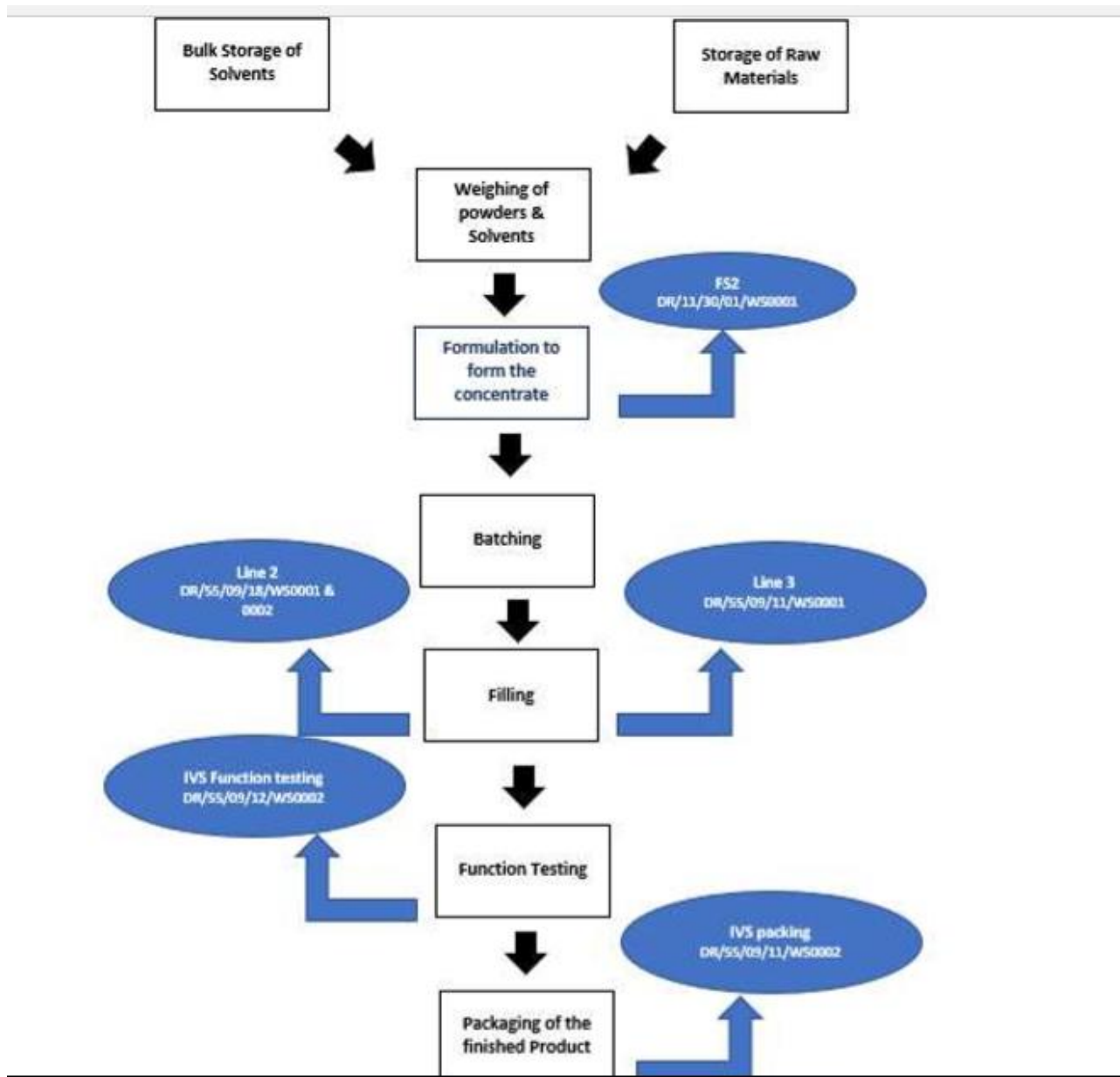
### Bulk Tank Storage

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
Ethanol DR/11/15/11/VES001	Storage	2021	Stainless Steel 316	58,860 L	Bunded

## **2. Inhalation Processes:**

This process comprises the following steps:

- Dispensing / weighing
- Mixing
- Filling
- Function Testing

Process flow- Inhalation ProcessDispensing / 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.



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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: -

<b>Activity</b>	<b>Description of specified activity</b>	<b>Limits of specified activity</b>
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.

<b>Substance</b>	<b>Source</b>	<b>Emission Limit</b>	<b>Monitoring Method – (as recommended by the Source Testing Association)</b>	<b>Monitoring Frequency</b>
Particulate matter	All emission points listed in Table 4 below	50 mg/Nm <sup>3</sup> 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
<b>Notes:</b> 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.

<b>Table 3– Total Emission Limit</b>			
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><b>Compliance is achieved if:</b> 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 <b>PLUS</b> the fugitive releases.</p> <p>Total Emission = O<sub>1</sub> + Fugitive</p> <p><b>and</b> 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> $\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100 \text{ is equal to or less than the total emission limit value}$			
<b>NOTE</b> the fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container			

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

<b>Table 4 – Emission Monitoring Points</b>					
Ref	Emissions Ref.	System Ref	Application	Location	Monitoring
1	IVS: Line 3	DR/55/09/11/WS0001	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
2	IVS: Line 3	DR/55/09/11/WS0002	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
3	IVS: Function Tester/LAC/BAI Pilot pressure fill	DR/55/09/12/ WS001	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
4	IVS: Function Tester/LAC/BAI Pilot pressure fill	DR/55/09/12/ WS002	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
5	IVS: Line 2	DR/55/09/18/WS001	Wet Scrubber	Plant Room 1 DR1.075	Manual extractive
	IVS Line 2	DR/55/09/18/WS002	Wet Scrubber	Plant Room 1 DR1.075	Manual extractive
6	IVS: Formulation Suite	DR/55/30/01/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.*

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### 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 = O<sub>1</sub> + 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<sub>1</sub> + I<sub>2</sub>

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:

**I<sub>1</sub>** 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 (I<sub>1</sub>) 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 (I<sub>1</sub>) = IS + PS – FS

**O<sub>8</sub>** Is the quantity of organic solvents contained in mixtures recovered for reuse.

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## Solvent Management Plan

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

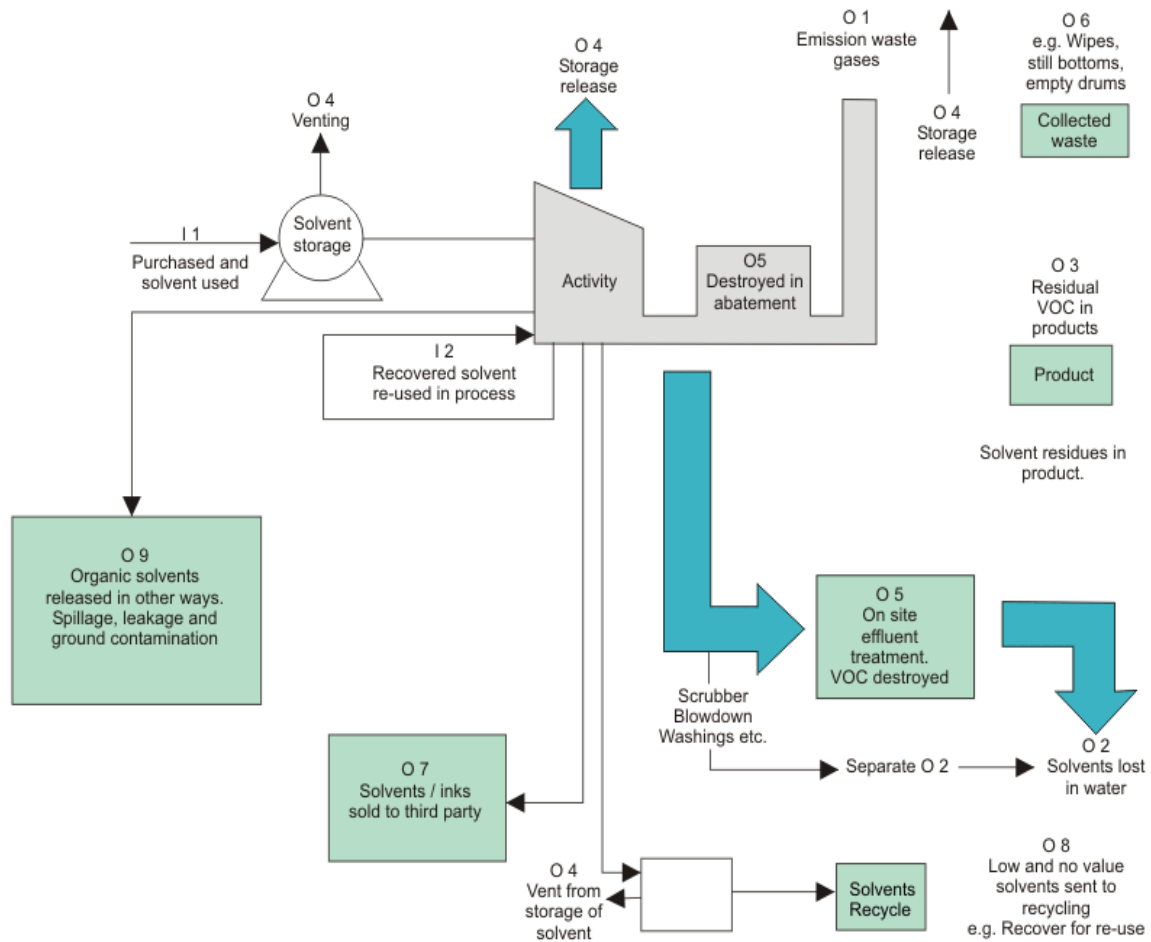
### Inputs of Organic Solvent in the time frame over which the mass balance is being calculated (I)

- I<sub>1</sub> 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).
- I<sub>2</sub> 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)

- O<sub>1</sub> Emissions in waste gases.
- O<sub>2</sub> Organic solvents lost in water, if appropriate taking into account waste water treatment when calculating O<sub>5</sub>.
- O<sub>3</sub> The quantity of organic solvents which remains as contamination or residue in products output from the process/activity.
- O<sub>4</sub> 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.
- O<sub>5</sub> 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 O<sub>6</sub>, O<sub>7</sub> or O<sub>8</sub>).
- O<sub>6</sub> Organic solvents contained in collected waste.
- O<sub>7</sub> Organic solvents, or organic solvents contained in mixtures, which are sold or are intended to be sold as a commercially valuable product.
- O<sub>8</sub> Organic solvents contained in mixtures recovered for reuse but not as input into the process/activity, as long as not counted under O<sub>7</sub>.
- O<sub>9</sub> Organic solvents released in other ways.

**Solvent Management Plan Inputs and Outputs**

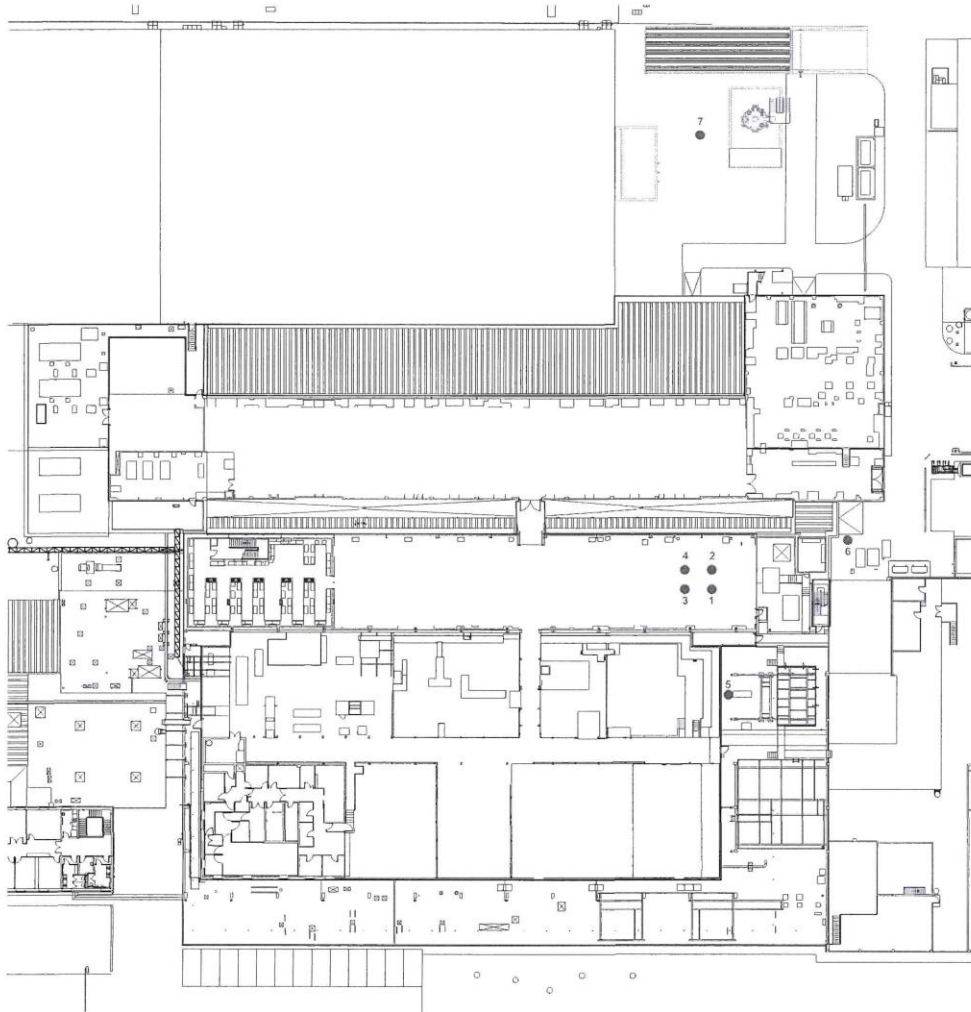


<p>Solvent Management Plan</p> <p>Consumption = I 1 - O 8                  Actual solvent emission = I 1 - O 5 - O 6 - O 7 - O 8                  Fugitive emission (F) = I 1 - O 1 - O 5 - O 6 - O 7 - O 8                  OR                  Fugitive emission (F) = O 2 + O 3 + O 4 + O 9</p>	<p>Solvent 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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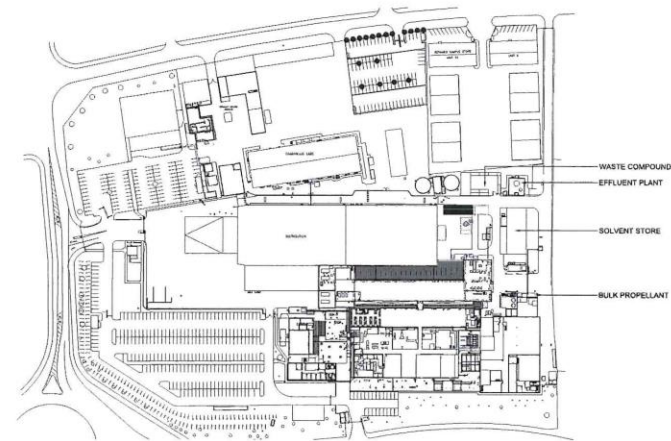


Appendix 1

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: LINE 3	DR/55/09/11/WS0002	WET SCRUBBER	PLANT ROOM 2 DR1.073
3	IVS: FUNCTION TESTER / LAC / BAI PILOT PRESSURE FILL	DR/55/09/12/WS0001	WET SCRUBBER	PLANT ROOM 2 DR1.073
4	IVS: FUNCTION TESTER / LAC / BAI PILOT PRESSURE FILL	DR/55/09/12/WS0002	WET SCRUBBER	PLANT ROOM 2 DR1.073
5	IVS: LINE 2	DR/55/09/18/WS0001	WET SCRUBBER	PLANT ROOM 1 DR1.075
	IVS: LINE 2	DR/55/09/18/WS0002	WET SCRUBBER	PLANT ROOM 1 DR1.075
6	IVS: FORMULATION SUITE 2	DR/55/30/01/WS0001	WET SCRUBBER	EXTERNAL BOILER HOUSE ANNEX DRG.287
7	BULK STORAGE OF ETHANOL	DR/11/15/11	BULK ETHANOL	PEBBLE BEACH



14.07.2023	C	WCH/LS/0001	UPDATER REFERENCE TABLE
01.03.2023	A	WCH/LS/0002	ADDED BULK ETHANOL
04.04.2021	A	WCH	FIRST RELEASE
DATE	REV	ISS/ CH NUMBER	DESCRIPTION
			<b>Kindeva</b> DRUG DELIVERY
			WCH/LS/0001
			WCH/LS/0002
			WCH/LS/0003
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			WCH/LS/0091
			WCH/LS/0092
			WCH/LS/0093
			WCH/LS/0094
			WCH/LS/0095
			WCH/LS/0096
			WCH/LS/0097
			WCH/LS/0098
			WCH/LS/0099
			WCH/LS/0100

## 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.