

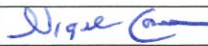





## 2012 Annual Environmental Report

For

**TopChem Pharmaceuticals Limited,  
Ballymote Business Park,  
Carrownanty,  
Ballymote,  
Co Sligo.**

**License Number: PO828-01**

<u>Name</u>	<u>Title</u>	<u>Signature</u>	<u>Date</u>
Nigel Cannon	General Manager		25/09/2013
Frances King	QA Manager		25/09/2013
Brian Murphy	Production Administrator		25/09/13
Dr Donal Coveney	Managing Director		25/09/2013

**Table of Contents:**

<b>Section</b>	<b>Topic</b>	<b>Page Number</b>
<b>1.0</b>	<b>Introduction</b>	3
1.1	Company Details	3
1.2	Activities	3
1.3	Environmental Policy	4
1.4	Environmental Management of the Company / Company Structure	4
<b>2.0</b>	<b>Resource Information</b>	6
2.1	Resource Consumption	6
2.2	Waste	12
2.3	Energy and Water Usage	28
2.4	Environmental Incidents and Complaints	28
<b>3.0</b>	<b>Environmental Management of Activity</b>	29
3.1	Environmental Objectives and Targets 2012	29
3.2	Environmental Management Report	30
3.3	Environmental Management Proposals 2013	31
<b>4.0</b>	<b>Financial Provision</b>	32
<b>5.0</b>	<b>Licence Specific Reports</b>	32
5.1	Pollutant Release Transfer Register (PRTR)	32
5.2	Residual Management Plan	32
5.3	Solvent Management Plan	32
5.4	Environmental Liability Risk Assessment (ELRA)	35
Appendix	Appendix 1: AER Returns Worksheet	N/A

## 1.0 Introduction

As per condition 11.8 of the TopChem Pharmaceuticals Limited Integrated Pollution Prevention & Control License, License Register Number P0828-01, attached is the Annual Environmental Report for the site covering period January 1<sup>st</sup> 2012 to December 31<sup>st</sup> 2012.

### 1.1 Company Details

TopChem Pharmaceuticals Limited is located in the Ballymote Business Park, Carrownanty, Ballymote, Co Sligo (National Grid Reference - 565818, 815634) where it is operating from a building leased from Ballymote Community Enterprise Limited. On February 20<sup>th</sup> 2008, TopChem Pharmaceuticals was granted an Integrated Pollution Prevention & Control (IPPC) license from the Environmental Protection Agency.

### 1.2 Activities

The IPPC License authorises TopChem Pharmaceuticals Limited to carry out the following activity at the site;

*The use of a chemical or biological process for the production  
Of basic pharmaceutical products.*

*NACE Code - 2120*

*RBME Risk Category – P-C2*

To date TopChem Pharmaceuticals has been involved in the manufacture of the following products at the facility;

- Malathion
- Benzyl Benzoate
- PGX-17
- Bretylium Tosylate
- Salicylic Acid
- 2,4 Dichlorobenzyl Alcohol
- Thiamine Hydrochloride
- Ethacrynic Acid

In 2012, Salicylic Acid and 2,4 Dichlorobenzyl Alcohol were not manufactured, Benzyl Benzoate and PGX-17 production remained steady year on year, although production on PGX -17 has now stopped since July 2012 due to customer demand, there were increases in the volumes of Bretylium Tosylate and Thiamine Hydrochloride produced and one new product was introduced namely Ethacrynic Acid.

During 2012 there were some internal modifications made to the layout in the Stores and Production Laboratory areas. In the stores, racking was installed for storing consumable supplies and archiving QA documentation. In the Production Laboratory, partitions were installed around 1 fume hood to improve controls when manufacturing products in the area. No other changes were implemented to the facility during 2012.

### 1.3 Environmental Policy

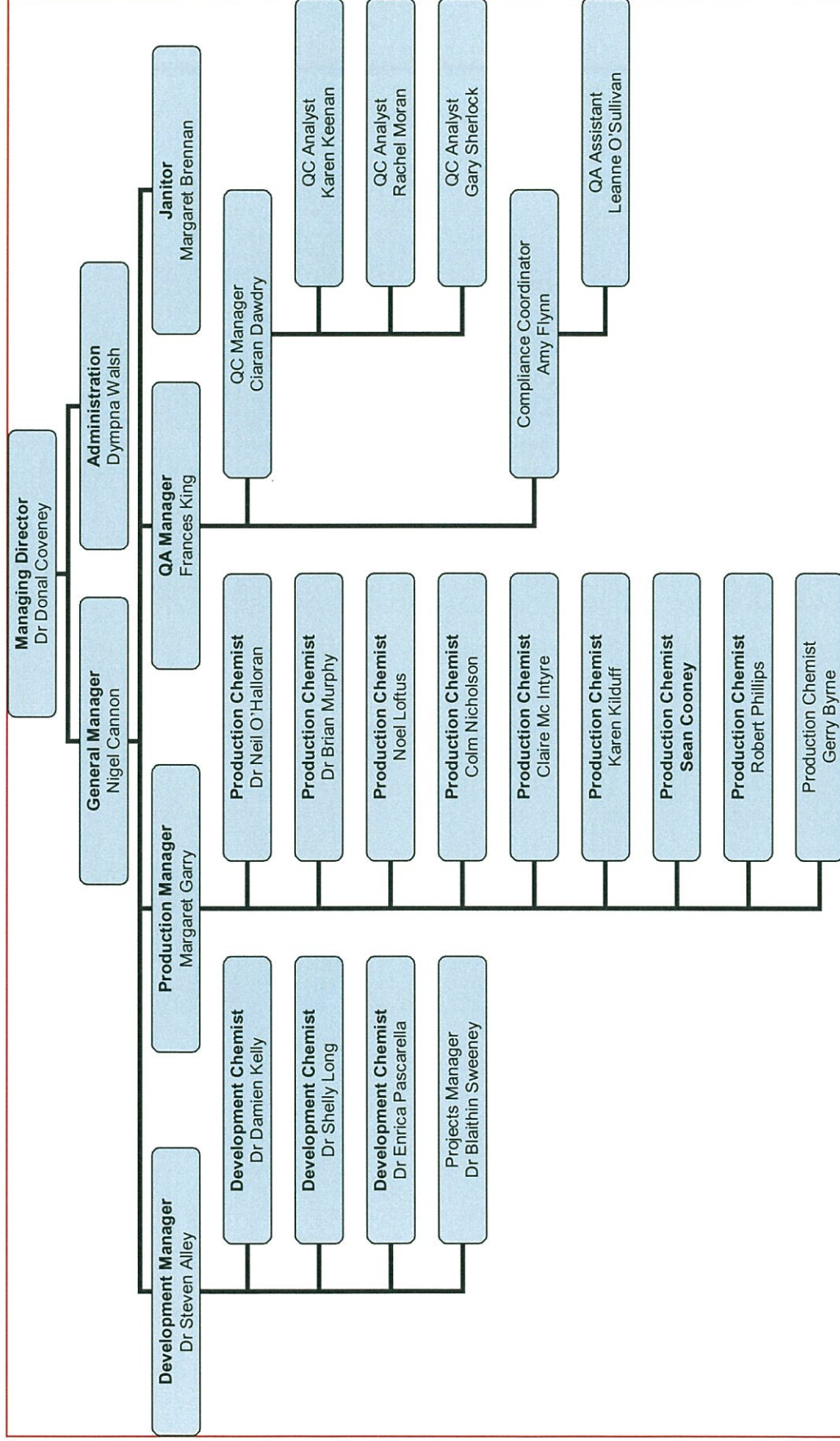
At TopChem Pharmaceuticals we continually assess all the environmental impacts associated with our activities. We aim to improve our management of the environment on a continuous basis. It is essential that all employees, visitors and contractors abide by all aspects of the environmental policy.

### 1.4 Environmental Management of the Company / Company Structure

Responsibility for the Environmental Management System at TopChem Pharmaceuticals currently falls under the remit of the General Manager. Under this present arrangement, the Production Manager acts as the deputy EHS Officer.

Environmental Management at the facility is co-ordinated through monthly EHS meetings, which involve participation from each of the core functions. i.e. Production, Quality and Development.

Management and Reporting Structure:



Each department has appointed an EHS representative so that issues identified at a departmental level can be addressed in a timely manner.

There is an EHS Storyboard installed on the first floor overlooking the Reception area. This is updated weekly and displays the following information;

- Metric - Incidents and Accident Reporting,
- Metric - Corrective Actions,
- Metric - Housekeeping Inspections,
- Metric - Hours Lost,
- Metrics - EHS Meetings, Fire Alarm checks, Fire Drills,
- EHS Goals and Objectives

There is also an Energy Management Notice Board installed, which is updated monthly and displays the following information;

- Energy Management Policy
- Green Team members
- Metric – Electricity usage on site
- Metric – Electricity Usage expressed per Employee
- Awareness information
- Energy Management / Green Goals and Objectives

## 2.0 Resource Information

### 2.1 Resource Consumption

This section covers details on Electricity usage and Raw Materials consumed in our Production Laboratory for the review period January 1<sup>st</sup> 2012 to December 31<sup>st</sup> 2012.

#### 2.1.1 Electricity

Electricity is the only source of energy used at TopChem Pharmaceuticals.

Bord Gais is the provider for electricity in Units 2 - 4 at the site.

Unit 1 is serviced by Electric Ireland.

In summary the Electricity Units consumed at the facility for the period under review are as documented in Table 1 overleaf;

**Table 1:**

Provider	Unit #	Consumption period	Usage ( KWH)
Electric Ireland	1	Nov 17 <sup>th</sup> 2011 – Jan 19 <sup>th</sup> 2013	796
Bord Gais	2	Jan 1 <sup>st</sup> – Dec 31 <sup>st</sup> 2012	760
Bord Gais	3 & 4	Jan 1 <sup>st</sup> – Dec 31 <sup>st</sup> 2012	183,400

TopChem Pharmaceuticals is currently leasing a block of 4 units in the Ballymote Business Park.

Units 3 & 4 are used for Manufacturing and all related support functions for the business.

Unit 1 is not used by TopChem Pharmaceuticals currently; hence electricity usage in this unit is extremely small. From Jan '12 to May '12 this unit was leased to a Third Party. The main contributor to the electricity usage is the outside lights.

Unit 2 is used for storage purposes only.

Unit 3& 4 was changed from a 24 Hour meter to a maximum demand meter in December 2011. As a result it is now possible to obtain day and night usage amounts which for 2012 were 109,800kwh & 73,600 kWh respectively.

The following changes resulted in increased electricity usage in 2012;

- Heaters on Air Handling Unit #2 were operational from 19.12.11.
- New outside lights were fitted.
- 120 Hour working week was introduced in the Production Laboratory in July 2012.

## 2.1.2 Raw Materials

Details of Process related Raw Materials, Intermediates, Products used / generated at the site during 2012 are as follows;

**Table 2:**

Product	Material	2012 Process Usage
Malathion	O,O Dimethylphosphorodithoic Acid Ammonium salt	9Kg
	Diethyl Maleate	6.5L
	NaHCO <sub>3</sub>	1Kg
	Hydroquinone	0.03Kg
	Triethylamine	0.025L
	Toluene	51.5L
	Conc. HCL	4L
	Process Water	23L
	Sodium Hydroxide	0.6Kg
	Sodium MetaBisulfite	14Kg
	Malathion (Product)	6Kg
Benzyl Benzoate	Benzyl Benzoate ( Crude)	120Kg
	Acetone	120L
	Benzyl Benzoate ( Product)	100Kg
PGX-17	Methyl 3 phenylpropionate	N/A
	Methyl dimethylphosphonate	N/A
	Butyl Lithium (2.5M in hexanes)	N/A
	Sodium Hypochlorite (2M)	1.2L
	2,2,6,6-Tetramethylpiperidine-1-oxyl (TEMPO)	0.013Kg
	Potassium Bromide	0.010Kg
	Lithium Chloride	0.2Kg
	Diisopropyl ethylamine	0.25Kg
	(R)-(+),1,1-Diphenylprolinol	0.5Kg
	Trimethylboroxine	0.03L
	Benzoyl Corey Lactone / PGX4	0.25Kg
	Borane dimethylsulfide (10M in BH <sub>3</sub> )	0.14L
	Tetrahydrofuran	21.5L
	Methyl 'Butyl Ether	N/A
	Hydrochloric Acid (37%)	0.8L
	Purified Water	115L
Dichloromethane	112L	
Molecular Sieves 3A	0.5Kg	



Product	Material	2012 Process Usage
PGX-17 continued	Ethyl Acetate	134L
	Hexanes	5.4L
	Acetonitrile	2.2L
	Toluene	3L
	Methanol	9.75L
	Sodium Sulfate	0.25Kg
	Sodium Bicarbonate	0.05Kg
	Sodium Chloride	13.5Kg
	Triethylamine	0.6L
	Acetone	5.4L
	Potassium Carbonate	0.08Kg
	Sodium Nitrite	0.02Kg
	5% Palladium on Carbon	0.015Kg
	Imidazole	0.13Kg
	Triethylchlorosilane	0.55Kg
	Diisobutylaluminium Hydride in Toluene 1M	1.8L
	4-carboxybutyl-triphenylphosphonium bromide (CTTP-Br)	0.8Kg
	Potassium tert-Butoxide 1M in THF	3.3L
	1,8-Diazabicyclo[5.4.0]undec-7-ene	1.4Kg
	2-Iodopropane	1.5Kg
	Magnesium Sulphate anhydrous	3Kg
	Silica-60	18Kg
	Heptane Fraction	211L
	Filter Agent	0.1Kg
	Ethanol	6L
	N,N-Dimethylformamide anhydrous	1.7L
	Sodium Hydrogen Sulphate	0.9Kg
	Citric Acid Monohydrate	0.28Kg
	Hydrogen Gas	1 Cylinder
	PGX-3	N/A
PGX-6	0.25Kg	
PGX-7	0.34Kg	
PGX-17 (Product)	0.45Kg	
Bretylum Tostylate	2-Bromobenzyl Bromide	57Kg
	Dimethylamine Hydrochloride	N/A
	Sodium Hydroxide	N/A
	Hydrochloric Acid (37%)	40Kg
	Methyl Butyl Ether (MTBE)	171L

Product	Material	2012 Process Usage
Bretylum Tostylate continued	Purified Water	61L
	Ethyl-p-Toluenesulphonate	40Kg
	Acetone	310L
	Ethyl Acetate	416L
	Sodium Hydroxide 20%	49.5Kg
	Dimethylamine Solution 40%	70.5Kg
	Bretylum Tosylate (Product)	70Kg
Salicylic Acid	Hydrochloric Acid (37%)	0
	Ethanol	
	Purified Water	
	Acetylsalicylic Acid	
	Salicylic Acid (Product)	
Dichlorobenzyl Alcohol	Hydrochloric Acid (37%)	0
	Sodium Hydroxide	
	Sodium Chloride	
	Heptane Fraction	
	Sodium Bicarbonate	
	Ethanol	
	Purified Water	
	tert-Butyl methyl ether	
	2,4 Dichlorobenzylaldehyde	
	Sodium Borohydride	
	Dichlorobenzyl Alcohol (Product)	
Thiamine Hydrochloride	Purified Water	470L
	Thiamine Hydrochloride USP	588Kg
	Isopropyl Alcohol	3560L
	Thiamine Hydrochloride (Product)	490Kg
Ethacrynic Acid	Hydrochloric Acid (37%)	1.4L
	Toluene	9.2L
	Sodium Chloride	1.3Kg
	Purified Water	3L
	Ethyl Acetate	10.4L
	Dimethylamine Hydrochloride	0.57Kg
	tert-Butyl methyl ether	12L
	Acetic Acid	2L
	Paraformaldehyde	0.24Kg
	Isopropyl Alcohol	5L
	(4-butanoyl-2,3 Dichlorophenoxy) acetic acid	2Kg

Product	Material	2012 Process Usage
Ethacrynic Acid continued	Sodium Pyrophosphate	5.6Kg
	Ethacrynic Acid (Product)	1Kg

## 2.2 Waste

There are four types of wastes generated at TopChem Pharmaceuticals which are as follows;

- Domestic Waste
- Mixed Recyclable Waste
- Hazardous Solid Waste
- Hazardous Liquid Waste

For Domestic & Mixed Recyclable waste, Barna Waste Disposal & Recycling is the approved waste disposal contractor.

For Hazardous waste (Solid & Liquid), Soltec Ireland Limited and SRCL, trading as ECO Safe Systems are the approved waste disposal contractors.

The following is a summary of the quantity of waste collected from TopChem Pharmaceuticals during the review period Jan 2012 – Dec 2012.

**Table 3:**

<b>Waste Type</b>	<b>Quantity</b>
Domestic Waste	0.66 Tonnes
Mixed Recyclables	2.16 Tonnes

The mixed recyclables collected by Barna Waste Disposal & Recycling are delivered to its facility in Carrowbrowne, Galway. Mixed recyclables are fed into their picking station where they are sorted into their individual waste fractions by a combination of machine (called a ballistic separator) and manual picking. Once separated materials are baled, stored and transferred off site to approved brokers for recycling.

Note:

- 1100Liter Mixed Recyclable bin = 80kg (this is the standard weight used by Barna Waste Disposal & Recycling in 2012 as they have no weighing system installed on their lorries as yet).
- The 240 Litre Domestic Bins is weighed by Barna Waste Disposal & Recycling.

The domestic waste quantity has increased from 0.53 Tonnes in 2011 to 0.66 Tonnes in 2012 i.e. 25% increase. The volume of mixed recyclables generated from the facility decreased from 2.36 Tonnes in 2011 to 2.16 Tonnes in 2012, i.e. a decrease of 8%.

Hazardous Waste Disposal 2012:

**Table 4:**

Solid Waste: ( Total 1942Kgs)

Month	Date	Provider	C1 Number	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-site	Liquid waste Secondary Recovery location	Use for Residue waste
Jan-12	16/01/2012	Eco-Safe Systems Limited	SO000132	145	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Feb-12	15/02/2012	Eco-Safe Systems Limited	SO000139	127	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Feb-12	15/02/2012	Eco-Safe Systems Limited	SO000139	88	Pallet	Contaminated glassware	Glassware	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Feb-12	27/02/2012	Eco-Safe Systems Limited	SO000184	124	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel

Month	Date	Provider	C1 Number	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-site	Liquid waste Secondary Recovery location	Use for Residue waste
<b>Apr-12</b>	05/04/2012	Eco-Safe Systems Limited	<b>SO000191</b>	170	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
<b>May-12</b>	10/05/2012	Eco-Safe Systems Limited	<b>SO000364</b>	130	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	121	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	145	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	187	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel

Month	Date	Provider	C1 Number	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-site	Liquid waste Secondary Recovery location	Use for Residue waste
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	139	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Nov-12	01/11/2012	Eco-Safe Systems Limited	SO000659	134	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314235	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	112	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314888/2	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	132	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314888/2	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	115	1000	Solid Flammable Waste	Toluene contaminated rags	IE 314888/2	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel

Month	Date	Provider	C-1 Number	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-site	Liquid waste Secondary Recovery location	Use for Residue waste
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	23	Box	Contaminated glassware	Glassware	IE 314888/4	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	25	Box	Contaminated glassware	Glassware	IE 314888/4	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	25	Box	Contaminated glassware	Glassware	IE 314888/4	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belgium. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel



**Table 5:**

Liquid Waste: (Total 12,682Kgs)

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Jan-12	16/01/2012	Eco-Safe Systems Limited	SO000132	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314043	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
Jan-12	16/01/2012	Eco-Safe Systems Limited	SO000132	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314043	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
Jan-12	16/01/2012	Eco-Safe Systems Limited	SO000132	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314043	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
Jan-12	16/01/2012	Eco-Safe Systems Limited	SO000132	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314043	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Feb-12	15/02/2012	Eco-Safe Systems Limited	SO000139	208	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
Feb-12	15/02/2012	Eco-Safe Systems Limited	SO000139	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
Feb-12	15/02/2012	Eco-Safe Systems Limited	SO000139	208	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
Feb-12	15/02/2012	Eco-Safe Systems Limited	SO000139	226	200	Water	Basic Aqueous	DCC004877	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
Feb-12	27/02/2012	Eco-Safe Systems Limited	SO000184	210	200	Solvent Liquid Waste	Non Chlorinated	IE 314226	REMONDIS Industrie Service GmbH, Niederlassung Bramsche, Am Kanal 9, D 49565 Bramsche.	Secondary Fuel
Feb-12	27/02/2012	Eco-Safe Systems Limited	SO000184	210	200	Solvent Liquid Waste	Non Chlorinated	IE 314226	REMONDIS Industrie Service GmbH, Niederlassung Bramsche, Am Kanal 9, D 49565 Bramsche.	Secondary Fuel
Feb-12	27/02/2012	Eco-Safe Systems Limited	SO000184	210	200	Solvent Liquid Waste	Non Chlorinated	IE 314226	REMONDIS Industrie Service GmbH, Niederlassung Bramsche, Am Kanal 9, D 49565 Bramsche.	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
<b>Apr-12</b>	05/04/2012	Eco-Safe Systems Limited	<b>SO000191</b>	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
<b>Apr-12</b>	05/04/2012	Eco-Safe Systems Limited	<b>SO000191</b>	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
<b>Apr-12</b>	05/04/2012	Eco-Safe Systems Limited	<b>SO000191</b>	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
<b>Apr-12</b>	05/04/2012	Eco-Safe Systems Limited	<b>SO000191</b>	230	200	Water	Basic Aqueous	DCC004877	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
<b>Apr-12</b>	05/04/2012	Eco-Safe Systems Limited	<b>SO000191</b>	210	200	Chlorinated	Chlorinated	DCC004877	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
<b>May-12</b>	10/05/2012	Eco-Safe Systems Limited	<b>SO000364</b>	196	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
May-12	10/05/2012	Eco-Safe Systems Limited	SO000364	100	200	Chlorinated	Chlorinated	DCC005726	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
May-12	23/05/2012	Eco-Safe Systems Limited	SO000375	195	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
May-12	23/05/2012	Eco-Safe Systems Limited	SO000375	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314382	Umweltservice Lindenschmidt KG, Krombacher Strabe 42-46 , 57223 Kreuztal - Krombach Germany. Licence Number is E97095037	Secondary Fuel
May-12	23/05/2012	Eco-Safe Systems Limited	SO000375	260	200	Chlorinated	Chlorinated	DCC005726	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
May-12	23/05/2012	Eco-Safe Systems Limited	SO000375	247	200	Chlorinated	Chlorinated	DCC005726	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
May-12	23/05/2012	Eco-Safe Systems Limited	SO000375	258	200	Chlorinated	Chlorinated	DCC005726	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
May-12	23/05/2012	Eco-Safe Systems Limited	SO000375	228	200	Water	Basic Aqueous	IE 314151	Recyfuel B4480 Zoning, Industriel D'Ehein, Englis, Belguim. Licence D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	204	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
<b>Sep-12</b>	24/09/2012	Eco-Safe Systems Limited	<b>SO000576</b>	204	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	204	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	204	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	205	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	208	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	208	200	Solvent Liquid Waste	Non Chlorinated	IE 314511	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	198	200	Water	Basic Aqueous	IE 314511	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	200	200	Water	Basic Aqueous	IE 314511	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	210	200	Water	Basic Aqueous	IE 314511	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	205	200	Water	Basic Aqueous	IE 314511	Recyfuel B4480 Zoning, Industriel D'Ehein, Engis, Belguim. License D3200 / 61080 / RGPED / 2008 / 2 / AP	Secondary Fuel
Sep-12	24/09/2012	Eco-Safe Systems Limited	SO000576	207	200	Chlorinated	Chlorinated	DCC010055	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
Nov-12	01/11/2012	Eco-Safe Systems Limited	SO000659	240	200	Water	Basic Aqueous	DCC011462	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Nov-12	01/11/2012	Eco-Safe Systems Limited	SO000659	240	200	Water	Basic Aqueous	DCC011462	Rilita Environmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	203	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	204	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel



Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/10	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Nov-12	29/11/2012	Eco-Safe Systems Limited	SO000657	220	200	Water	Basic Aqueous	DCC012179	Rilta Evironmental Ltd, 1A Allied Ind. Est, Kylemore Road, Ballyfermot, Dublin 10	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	206	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/11	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	210	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/11	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Dec-12	20/12/2012	Eco-Safe Systems Limited	SO000722	210	200	Solvent Liquid Waste	Non Chlorinated	IE 314511/11	Avanti Environmental Group Ltd, Advanti Treatment & Transfer Station, Charley Wood Road, Knowsley Ind Est, Liverpool, Merseyside L33 7SG	Secondary Fuel
Dec-12	14/12/2012	Soltec Ireland Limited	SO000867	200	200	Water	Basic Aqueous	N/A	Soltec Ireland Limited, Zone A, Mullingar Business Park, Mullingar, Co Westmeath	Used in the Production of Thinners.
Dec-12	14/12/2012	Soltec Ireland Limited	SO000867	200	200	Water	Basic Aqueous	N/A	Soltec Ireland Limited, Zone A, Mullingar Business Park, Mullingar, Co Westmeath	Used in the Production of Thinners.

Month	Date	Provider	C1 Number Pickup	Quantity (Kgs)	Quantity (L)	Chemical Composition of Waste	Waste Stream	C1 Number Off-Site	Solid waste Secondary Recovery location	Use for Residue waste
Dec-12	14/12/2012	Soltec Ireland Limited	SO000867	200	200	Solvent Liquid Waste	Non Chlorinated	N/A	Soltec Ireland Limited, Zone A, Mullingar Business Park, Mullingar, Co Westmeath	Used in the Production of Thinners.
Dec-12	14/12/2012	Soltec Ireland Limited	SO000867	200	200	Solvent Liquid Waste	Non Chlorinated	N/A	Soltec Ireland Limited, Zone A, Mullingar Business Park, Mullingar, Co Westmeath	Used in the Production of Thinners.
Dec-12	14/12/2012	Soltec Ireland Limited	SO000867	200	200	Solvent Liquid Waste	Non Chlorinated	N/A	Soltec Ireland Limited, Zone A, Mullingar Business Park, Mullingar, Co Westmeath	Used in the Production of Thinners.

2011 & 2012 Hazardous Waste Disposal Comparison:

**Table 6:**

<b>Waste Stream</b>	<b>2011 Qty</b>	<b>2012 Qty</b>	<b>Variance (%)</b>	<b>Comment</b>
<b>Solid Waste</b>	1793 Kgs	1781 Kgs	-0.7%	No real change YoY
<b>Contaminated Glassware</b>	0	161Kgs		Segregated from Solid waste in 2012
<b>Non Chlorinated Waste</b>	5010 Litres	8000 Litres	+59.7%	Increase in Production output for Bretylium Tosylate & Thiamine Hydrochloride.
<b>Chlorinated Waste</b>	3090 Litres	1200 Litres	-61.2%	Waste stream was associated primarily with PGX 17 which ended mid 2012.
<b>Basic Aqueous Waste</b>	1840 Litres	2400 Litres	+30.4%	Increase in Bretylium Tosylate Production output
<b>Mercury Waste</b>	50 Litres	0 Litres	-100%	
<b>Acidic Waste</b>	125 Litres	0 Litres	-100%	

### 2.3 Energy & Water Usage

Electricity is the only source of energy used in TopChem Pharmaceuticals.

Refer to section 2.1 for consumption details for the period under review.

As regards Water Usage at the site, any water required in the Production Process is purchased as a raw material. All remaining water requirements at the facility are for domestic purposes only, i.e. Toilets, Kitchen. Water is also used in the Production Laboratory for equipment cooling but this is non process contacting.

During the period under review TopChem Pharmaceuticals purchased 5650L of Purified Water – 2450L from Rice Steele, Unit 31 2<sup>nd</sup> Avenue, Cookstown Industrial Estate, Tallaght, Dublin 24 and 3200L from Ultra Pure Laboratories, Foxford, Co Mayo for use in the Production Process.

### 2.4 Environmental Incidents & Complaints

During the review period January 1<sup>st</sup> 2012 to December 31<sup>st</sup> 2012, no environmental complaints were received by TopChem Pharmaceuticals Limited.

There was one incident at the TopChem Pharmaceuticals site which was reported to the Environmental Protection Agency. This occurred on 18<sup>th</sup> November 2012. The incident involved the uncontrolled release of approx 1.5L of HPLC waste down the sink in the QC / DV Laboratory. The composition of the 1.5L was 75% water, 15% methanol, 8% acetonitrile and 2% other minor non hazardous ingredients.

The following is an overview of Environmental incidents reported within TopChem Pharmaceuticals during the period Jan 1<sup>st</sup> 2012 – Dec 31<sup>st</sup> 2012;

- There was a build up of a mould around the jamb of the Chemical Store door. The mould was removed and there was no impact on the environment.
- There was a spillage of sodium bisulphite waste as a result of a breakage to a storage vessel. The incident was treated as a safety issue as the spill was contained with no impact on the environment.
- A 200L solvent drum fell off a trolley during transfer from the Production Laboratory to Unit 2. The incident was treated as a safety issue as the spill was contained with no impact on the environment.

### 3.0 Environmental Management of Activity

#### 3.1 Environmental Objectives & Targets

Table 7 below is an update on each of the Objectives agreed for the period Jan 1<sup>st</sup> 2012 – Dec 31<sup>st</sup> 2012.

**Table 7:**

Objective	Status
Install system to collect rain water for servicing Toilets	Not completed. On the list of tasks to be completed in 2013.
Change t8 Fluorescents to t5 fluorescents in the Production Laboratory	Complete.
Install light sensors in the back stairwell, Production Laboratory, Employee Entrance and Toilets.	Light sensor installed in the back stairwell and toilets. It was decided not to install light sensors in the Production Laboratory. Sensors at the employee entrance to be fitted in 2013.
Connect external lights servicing Units 1 & 2 to time clocks.	Complete
Implement Paper Reduction Initiative in Production	Only printing Standard Operating Procedures that are relevant to the Production area.
Implement Paper Reduction Initiative in QA	PGX17 Manufacturing Batch Records were scanned to the customer as opposed to printing. Standard Operating Procedures were only issued to Departments where they are relevant.

### 3.2 Environmental Management Report

The key environmental objective for the company in 2012 was to continue to track all conditions in the company's IPPC License (P0828-01) and ensure that the high level of environmental compliance achieved in previous years was maintained.

With this in mind the following is an overview of the environmental accomplishments for the facility during 2012,

- The company received no environmental complaints during the Year.
- Approval received from the EPA for Ethacrynic Acid, which was introduced in Q1 2012.
- All mobile bunds used at TopChem Pharmaceuticals were inspected on a regular basis and all were found to be satisfactory.
- An occupational air survey was conducted in the Production Laboratory in May 2012 by KD Environmental, 1 Swiftbrook Glen, Virginia, Co Cavan. Three employees were monitored and the National Authority for Occupational Safety & Health, 2007 Code of Practice for the safety, Health & Welfare at Work (Chemical Agents) Regulations, 8 hour TWA Limit for Total and Respirable Particulates was not exceeded for any personnel monitored.
- An Occupational Noise Survey was completed by Tobin Consulting Engineers, Block 10-4, Blanchardstown Corporate Park, Dublin 15 in May 2012. The maximum unprotected exposure time as worker can spend at any piece of plant was calculated and the lower exposure action value, upper exposure action value and the exposure action limit value were all complied with. Therefore no proprietary noise mitigation, signage, PPE or limiting of shift times is required.
- The company's EHS Goals & Objectives and associated key performance indicators were updated on a weekly basis and results posted on a dedicated Environmental Health & Safety notice board.
- On site environmental communications were maintained with employees through planned EHS Meetings.
- The company continued to use approved waste disposal contractors for disposal of hazardous, domestic and recyclable waste streams generated on site.
- The company continued to facilitate EHS training on site in areas such as basic chemical awareness, use of spill kits, manual handling and fire safety training.
- Monthly Housekeeping Inspections were conducted on site.
- The company facilitated an OEE inspection on 29/2/12. There were no non-compliances noted during the inspection. There were 2 observations noted. The EPA contact detail to be included to the Emergency Response Procedure and the Accident Prevention Procedure to be updated on annual basis.

Overall, the company continued to display high levels of control & employee awareness on environmental health and safety matters during 2012.

### 3.3 Environmental Management Proposals for 2013

**Table 8:**

<b>Objective</b>	<b>Responsibility</b>	<b>How objective will be achieved</b>	<b>Timeframe</b>
Install system to collect rain water for servicing Toilets	EHS Officer	Identify Service Contractor and implement accordingly	Q1- Q4 2013
Assess if the photocopier / scanner / printer / fax can revert to 'Hibernate mode' when not in use	EHS Officer	Purchase Equipment which has a 'hibernate' function built in.	Q1 2013
Install light sensors in the employee entrance, landing over reception, main office in admin, Visitor Toilet, Unit 1 & Unit 2.	EHS Officer	Identify Service Contractor and implement accordingly	Q2 2013
Implement 'red card' system which acts as a reminder for employees to switch their computer to hibernate mode when not required.	QA Manager	Sign to be prepared for each computer user and Training completed.	Q1 2013
Implement Paper Reduction Initiative	QA	Print double sided documents.	Q1 – Q4 2013
Assess the economic and environmental benefits of a continuous supply of hot water in the kitchen	EHS Officer	Replace kettle with Boiler system.	Q1 – Q4 2013

#### **4.0 Financial Provision**

TCP Ltd make allowances for financial provision as required under Condition No. 12 of licence no. P0828-01. Details of same can be referenced in the ELRA Report submitted to the Agency in March 2013.

#### **5.0 Licence Specific Reports**

##### **5.1 PRTR**

Attached are the following AER / PRTR files which were submitted to the Agency in March 2013.

- Facility ID and Activities sheet
- Releases to Air – nothing reported given TCP has no emissions to Air other than minor fugitive emissions.
- Releases to Water – Nothing reported given TCP has no emissions to Water.
- Releases to Waste Water or Sewer – Nothing recorded given TCP has no emissions to sewer other than wastes from Toilet and kitchen facilities and purified water from heating and cooling baths which are non product contacting.
- Releases to Land – Nothing reported given TCP has no emissions to Land.
- Treatment of Transfers of Waste

##### **5.2 Residual Management Plan**

Details can be referenced in the Residual Management Plan submitted to the Agency in March 2013.

##### **5.3 Solvent Management Plan**

As per condition 6.11.1, TCP must report on the use of solvents per each calendar Year as part of its AER.

As advised in the Solvent Management Plan submitted to the Agency in March 2013, due to the scale of the operation at TopChem Pharmaceuticals, only small volumes of solvents are used, hence there is no requirement for fugitive emissions monitoring or a solvent reduction plan.

The procurement, disposition and disposal of solvents are monitored on an ongoing basis under the auspices of our internal quality control and environmental health and safety systems.

The Table overleaf summarises Solvents consumed at TCP for the period January 1<sup>st</sup> 2012 – December 31<sup>st</sup> 2012.



Solvents & Water Usage in litres at TCP from January 1<sup>st</sup> 2012 to December 31<sup>st</sup> 2012

**Table 9:**

Month	Acetone	Methanol	MeCN	EtOAc	Hexane	Heptane	THF	DCM	MTBE	EtOH	Toluene	IPA	Water*
Stock carried over 2011	240L	102.5L	22.5L	1064L	49L	222.2L	65.1L	788.2L	7.25L	18.5L	84.7L	824.6L	1265L
<b>Solvents ordered 2012</b>													
Jan-12	310L	10L	10L		10L	10L			30L				
Feb-12	245L	140L	35L	10L		40L				25L	5L	0	1600L
Mar-12	275L	100L	10L	10L	60L				10L	10L		200L	
Apr-12	310L	130L			10L							200L	800L
May-12													
Jun-12	50L	15L	20L	20L	15L	15L						1200L	
Jul-12	235L	10L	20L	5L			5L		50L	5L	5L		
Aug-12	245L	150L	20L				5L	10L	20L	10L	15L		
Sep-12	225L								75L			600L	850L
Oct-12	385L	125L				5L			150L			600L	
Nov-12	145L	150L	30L			5L			200L	20L	5L		2400L
Dec-12	200L												
<b>Total Ordered</b>	<b>2625L</b>	<b>830L</b>	<b>145L</b>	<b>45L</b>	<b>95L</b>	<b>75L</b>	<b>10L</b>	<b>10L</b>	<b>535L</b>	<b>70L</b>	<b>30L</b>	<b>2800L</b>	<b>5650L</b>
<b>Total</b>	<b>2865L</b>	<b>932.5L</b>	<b>167.5L</b>	<b>1109L</b>	<b>144L</b>	<b>297.2L</b>	<b>75.1L</b>	<b>798.2L</b>	<b>542.25L</b>	<b>88.5L</b>	<b>114.7L</b>	<b>3624.6L</b>	<b>6915L</b>
Remaining Stock End 2012	257.5L	110L	15L	12.5L	2.5L	5L	10L	42.5L	255L	22.5L	27.5L	252.5L	1015L
<b>Total Usage</b>	<b>2607.5L</b>	<b>822.5L</b>	<b>152.5L</b>	<b>1096.5L</b>	<b>141.5L</b>	<b>292.2L</b>	<b>65.1L</b>	<b>755.7L</b>	<b>287.25L</b>	<b>66L</b>	<b>87.2L</b>	<b>3372.1L</b>	<b>5900L</b>

MeCN = Acetonitrile  
 EtOAc = Ethyl Acetate  
 THF = Tetrahydrofuran  
 IPA = Isopropyl Alcohol  
 EtOH = Ethanol  
 MTBE = Methyl- tert-Butyl- Ether  
 DCM = Dichloromethane

Table 10 below provides an overview of the total solvents procured by TCP during the review period January 1<sup>st</sup> 2012 – December 31<sup>st</sup> 2012.

It also illustrates the opening and closing balances on site for 2012 together with new waste produced, shipped and a volume balancing result.

**Table 10:**

<b>Item</b>	<b>Unit</b>	<b>Quantity</b>
<b>Solvent Usage</b>	Litres	<b>9746.05</b>
<b>Opening Waste balance Jan 2012</b>		<b>552</b>
Non Chlorinated solvent waste -		245
Chlorinated solvent Waste -		137
Basic Aqueous –	Litres	170
Acidic –		0
Mercury -		0
<b>Net waste Recorded Jan 2012 – Dec 2012</b>		<b>12,284.5</b>
Non Chlorinated solvent waste -		8947
Chlorinated solvent Waste -	Litres	928.5
Basic Aqueous –		2409
Acidic –		0
Mercury -		0
<b>Closing Waste balance Dec 2012</b>		<b>740</b>
Non Chlorinated solvent waste -		555
Chlorinated solvent Waste -		21
Basic Aqueous –	Litres	164
Acidic –		0
Mercury -		0
<b>Waste shipped Jan 2012 – Dec 2012</b>		<b>12,200</b>
Non Chlorinated solvent waste -		8600
Chlorinated solvent Waste -	Litres	1200
Basic Aqueous –		2400
Acidic –		0
Mercury -		0
<b>Volume Balancing Result (Solvent Usage V's Waste Shipped &amp; Closing Balance at Year End )*</b>	<b>%</b>	<b>133%</b>

In summary, the volume of waste solvent produced exceeded the volume of solvent purchased by 33%. The reason for this is that a number of waste streams are diluted with purified water which is occasionally used as a manufacturing material.

5900L of Purified water was consumed within TCP in 2012. However, Purified water is not included in the overall solvent usage. Approximately 40% of the material purchased is used as a manufacturing material and in analytical testing in our QC laboratory. The remainder is consumed in cooling and heating baths.

#### 5.4 ELRA:

The ELRA Report was updated and submitted to the Agency in March 2013. During 2012, the following change, as previously advised to the Agency, was implemented on site;

- One new Product was introduced, namely Ethacrynic Acid.



Environmental Protection Agency

| PRTR# : P0828 | Facility Name : TopChem Pharmaceuticals Limited | Filename : P0828\_2012 (updated 200913).xls | Return Year : 2012 |

Guidance to completing the PRTR workbook

# AER Returns Workbook

Version 1.1.15

<b>REFERENCE YEAR</b>	2012
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**1. FACILITY IDENTIFICATION**

Parent Company Name	TopChem Pharmaceuticals Limited
Facility Name	TopChem Pharmaceuticals Limited
PRTR Identification Number	P0828
Licence Number	P0828-01

Waste or IPPC Classes of Activity

No.	class_name
5.16	The use of a chemical or biological process for the production of basic pharmaceutical products.

Address 1	Ballymote Business Park
Address 2	Carrownanty
Address 3	Ballymote
Address 4	County Sligo
	Sligo
Country	Ireland
Coordinates of Location	-8.52186 54.0885
River Basin District	IEWE
NACE Code	2120
Main Economic Activity	Manufacture of pharmaceutical preparations
<b>AER Returns Contact Name</b>	Nigel Cannon
<b>AER Returns Contact Email Address</b>	nigel@topchempharma.com
<b>AER Returns Contact Position</b>	General Manager
<b>AER Returns Contact Telephone Number</b>	071 91 89685
<b>AER Returns Contact Mobile Phone Number</b>	087 9162685
<b>AER Returns Contact Fax Number</b>	071 9197864
<b>Production Volume</b>	668.0
<b>Production Volume Units</b>	Kg
<b>Number of Installations</b>	1
<b>Number of Operating Hours in Year</b>	6000
<b>Number of Employees</b>	24
<b>User Feedback/Comments</b>	
<b>Web Address</b>	www.topchempharma.com

**2. PRTR CLASS ACTIVITIES**

Activity Number	Activity Name
4(e)	Installations using a chemical or biological process for the production on an industrial scale of basic pharmaceutical products

**3. SOLVENTS REGULATIONS (S.I. No. 543 of 2002)**

Is it applicable?	No
Have you been granted an exemption ?	No
If applicable which activity class applies (as per Schedule 2 of the regulations) ?	Not Applicable
Is the reduction scheme compliance route being used ?	No

**4. WASTE IMPORTED/ACCEPTED ONTO SITE**

[Guidance on waste imported/accepted onto site](#)

Do you import/accept waste onto your site for on-site treatment (either recovery or disposal activities) ?	No
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[Link to previous years emissions data](#)

[19414# P0828 P0828] Facility Name : TopChem Pharmaceuticals Limited | Filename : P0828\_2012 (updated 200913).xls | Return Year : 2012 | 25/09/2013 11:15

4.1 RELEASES TO AIR

SECTION A : SECTOR SPECIFIC PRTR POLLUTANTS

POLLUTANT	RELEASERS TO AIR		Please enter all quantities in this section in KGs	
	M/C/E	Method Used Designation or Description	Emission Point 1	QUANTITY
No. Annex II			T (Total) KG/Year 0.0	A (Accidental) KG/Year 0.0
			F (Fugitive) KG/Year 0.0	

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING PRTR POLLUTANTS

POLLUTANT	RELEASERS TO AIR		Please enter all quantities in this section in KGs	
	M/C/E	Method Used Designation or Description	Emission Point 1	QUANTITY
No. Annex II			T (Total) KG/Year 0.0	A (Accidental) KG/Year 0.0
			F (Fugitive) KG/Year 0.0	

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION C : REMAINING POLLUTANT EMISSIONS (As required in your Licence)

POLLUTANT	RELEASERS TO AIR		Please enter all quantities in this section in KGs	
	M/C/E	Method Used Designation or Description	Emission Point 1	QUANTITY
Pollutant No.			T (Total) KG/Year 0.0	A (Accidental) KG/Year 0.0
			F (Fugitive) KG/Year 0.0	

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

Additional Data Requested from Landfill operators

For the purposes of the National Inventory on Greenhouse Gases, landfill operators are requested to provide summary data on landfill gas (Methane) flared or utilised on their facilities to accompany the figures for total methane generated. Operators should only report their Net methane (CH4) emission to the environment under T(total) KG/yr for Section A: Sector specific PRTR pollutants above. Please complete the table below:

Please enter summary data on the quantities of methane flared and / or utilised	Method Used		Facility Total Capacity m3 per hour
	M/C/E	Designation or Description	
Total estimated methane generation (as per site model)	0.0		N/A
Methane flared	0.0		0.0 (Total Flaring Capacity)
Methane utilised in engines	0.0		0.0 (Total Utilising Capacity)
Net methane emission (as reported in Section A above)	0.0		N/A

4.2 RELEASES TO WATERS

[Link to previous years emissions data](#)

| PRTR# : P0828 | Facility Name : TopChem Pharmaceuticals Limited | Filename : P0828\_2012 (updated 200913).xls | Return Year : 2012 |

25/09/2013 11:15

SECTION A : SECTOR SPECIFIC PRTR POLLUTANTS

**Data on ambient monitoring of storm/surface water or groundwater, conducted as part of your licence requirements, should NOT be submitted under AER / PRTR Reporting as this or Please enter all quantities in this section in KGs**

RELEASES TO WATERS		QUANTITY					
POLLUTANT	Name	M/C/E	Method Used Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
No. Annex II					0.0	0.0	0.0

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING PRTR POLLUTANTS

**Please enter all quantities in this section in KGs**

RELEASES TO WATERS		QUANTITY					
POLLUTANT	Name	M/C/E	Method Used Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
No. Annex II					0.0	0.0	0.0

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION C : REMAINING POLLUTANT EMISSIONS (as required in your Licence)

**Please enter all quantities in this section in KGs**

RELEASES TO WATERS		QUANTITY					
POLLUTANT	Name	M/C/E	Method Used Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
Pollutant No.					0.0	0.0	0.0

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

4.3 RELEASES TO WASTEWATER OR SEWER

[Link to previous years emissions data](#)

IPRTR# : F0028 | Facility Name : TopChem Pharmaceuticals Limited | Release : F0028\_2012.rpt

SECTION A : PRTR POLLUTANTS

POLLUTANT		M/C/E		METHOD		Please enter all quantities in this section in KGs			
No. Annex II	Name	M/C/E	Method Code	Method Used	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
						0.0	0.0	0.0	0.0

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING POLLUTANT EMISSIONS (as required in your Licence)

POLLUTANT		M/C/E		METHOD		Please enter all quantities in this section in KGs			
Pollutant No.	Name	M/C/E	Method Code	Method Used	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
						0.0	0.0	0.0	0.0

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button



[Link to previous years emissions data](#)

| PRTR# : P0828 | Facility Name : TopChem Pharmaceuticals Limited | Filename : P0828\_2012 (updated 200913).xls | Return Year : 2012 | 25/09/2013 11:16

**4.4 RELEASES TO LAND**

**SECTION A : PRTR POLLUTANTS**

POLLUTANT		METHOD		Emission Point 1		T (Total) KG/Year		A (Accidental) KG/Year	
No. Annex II	Name	M/C/E	Method Used Designation or Description	Method Code	Description or Description				
						0.0	0.0	0.0	0.0

Please enter all quantities in this section in KGs

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

**SECTION B : REMAINING POLLUTANT EMISSIONS (as required in your Licence)**

POLLUTANT		METHOD		Emission Point 1		T (Total) KG/Year		A (Accidental) KG/Year	
Pollutant No.	Name	M/C/E	Method Used Designation or Description	Method Code	Description or Description				
						0.0	0.0	0.0	0.0

Please enter all quantities in this section in KGs

\* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

5. ONSITE TREATMENT & OFFSITE TRANSFERS OF WASTE

Please enter all quantities on this sheet in Tonnes

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Hazardous Waste Name and Licence/Permit No of Next Destination Facility	Hazardous Waste Name and Licence/Permit No of Recover/Disposer	Hazardous Waste Address of Next Destination Facility	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination (ie. Final Recoverer/Disposal Site) (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used						
To Other Countries	15 02 02	Yes	1,781	absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances	R1	M	Weighted	Abroad	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Recyfuel B4480 Zoning, Industrial D'Ehein, Engis, Belgium	Recyfuel B4480 Zoning, Industrial D'Ehein, Engis, Belgium	
To Other Countries	07 05 01	Yes	1,041	aqueous washing liquids and mother liquors	R1	M	Weighted	Abroad	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Recyfuel B4480 Zoning, Industrial D'Ehein, Engis, Belgium	Recyfuel B4480 Zoning, Industrial D'Ehein, Engis, Belgium	
Within the Country	07 05 01	Yes	1,156	aqueous washing liquids and mother liquors	R1	M	Weighted	Offsite in Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	1A Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	1A Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	
Within the Country	07 05 03	Yes	1,282	organic halogenated solvents, washing liquids and mother liquors	R1	M	Weighted	Offsite in Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	1A Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	1A Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	
To Other Countries	07 05 04	Yes	4,927	other organic solvents, washing liquids and mother liquors	R1	M	Weighted	Abroad	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Charley Wood Road, Knowsley Industrial Park, Merseyside, L33 7SG, United Kingdom	Charley Wood Road, Knowsley Industrial Park, Merseyside, L33 7SG, United Kingdom	
To Other Countries	07 05 04	Yes	2,646	other organic solvents, washing liquids and mother liquors	R1	M	Weighted	Abroad	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Unit 1A, Allied Industrial Estate, Kylemore Road Ballyfermot, Dublin 10, Ireland	Umweltservice Lindenschmidt KG, Krombacher Strabe 42 - 46,57223 Kreuztal, Krombach, Germany	Umweltservice Lindenschmidt KG, Krombacher Strabe 42 - 46,57223 Kreuztal, Krombach, Germany	
Within the Country	07 05 01	Yes	0.4	aqueous washing liquids and mother liquors	R1	M	Weighted	Offsite in Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	
Within the Country	07 05 04	Yes	0.6	other organic solvents, washing liquids and mother liquors	R1	M	Weighted	Offsite in Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	Zone A, Mullingar Business Park, Mullingar, Co Westmeath, Ireland	

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Haz.Waste - Name and Licence/Permit No of Next Destination Facility Haz.Waste: Name and Licence/Permit No of Recoverer/Disposer	Haz.Waste - Address of Next Destination Facility Non-Haz.Waste: Address of Recoverer/Disposer	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
To Other Countries	07 05 13	Yes	0.161	solid wastes containing dangerous substances	R1	M	Weighted	Abroad	ECO Safe Systems Limited,54-2 WCP-DC-09-1203-01	Unit 1A,Allied Industrial Estate,Kylemore Road Ballyfermot,Dublin 10,Ireland	Recyfuel B4480 Zoning:D3200 / 61080 / RGPED / 2008 / 2 / AP,Recyfuel B4480 Zoning,Industrial D'Ehein,Engls,...,Belgium	Recyfuel B4480 Zoning,Industrial D'Ehein,Engls,...,Belgium
To Other Countries	07 05 04	Yes	0.63	other organic solvents, washing liquids and mother liquors	R1	M	Weighted	Abroad	ECO Safe Systems Limited,54-2 WCP-DC-09-1203-01	Unit 1A,Allied Industrial Estate,Kylemore Road Ballyfermot,Dublin 10,Ireland	REMONDIS,12HRO03003,Industrie Service GmbH,Am Kanal	Industrie Service GmbH,Am Kanal 9,Bramsche,49565,Germany

\* Select a row by double-clicking the Description of Waste then click the delete button