



# Corporate Environment, Health, Safety and Energy Report 2013

**LEO PHARMA MANUFACTURING SITES**

**LEO<sup>®</sup>**



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# Environment, Health, Safety and Energy

Environment, Health, Safety and Energy (EHSE) is at the heart of LEO Pharma and we show this by striving to continuously improve the working environment for our people and thereby helping patients and communities. With this in mind, we have set ambitious EHSE targets, challenging ourselves to create new and better practices across our operations to minimise our environmental impact and to create a high safety performance culture.

One of the major global goals for 2015 is to have all current manufacturing sites certified according to ISO 14001 on environment and OHSAS 18001 on health and safety. LEO Pharma Dublin and Vernouillet already hold an ISO 14001 certificate. The rest of our sites will obtain the ISO 14001 certification by the end of 2015.

In regards OHSAS 18001 certification, LEO Pharma Cork received the OHSAS 18001 Certificate on 7 January 2013. LEO Pharma Ballerup and Esbjerg were re-certified in OHSAS 18001 and every effort must be made to keep up the good work in 2014. Unfortunately, LEO Pharma Dublin did not obtain their OHSAS 18001 certificate as planned, but we expect that it will be achieved in 2014.

At LEO Pharma, we want to be Best in Class - also when it comes to safety. A safe workplace without injuries supports our ambition to deliver products to the patient on time and emphasises our wish that employees feel safe at work.

One of the major initiatives in 2013 has been to put safety awareness even higher on the agenda than previously. Starting on 1 May 2013, we have launched

global environment, health and safety (EHS) campaigns each month throughout the year. This has increased awareness and we will continue this work going forward. In addition to global campaigns, the local manufacturing sites run campaigns relevant for their site.

We've made good progress against our EHSE strategy, but we can achieve more. As we look forward to the next five years, we can all help exceed our environmental commitments – challenging ourselves by continuing to reduce resources, waste and carbon even as our business grows. And better focus on ourselves and our colleagues by prioritising safety first.

I will also do my best in 2014 to improve our environment, health and safety performance to reach our goal of becoming Best in Class.

Yours sincerely  
Executive Vice President



Anders B. Spohr

## LEO Pharma Facts

LEO Pharma helps people achieve healthy skin. By offering care solutions to patients in more than 100 countries globally, LEO Pharma supports people in managing their skin conditions.

Founded in 1908 and owned by the LEO Foundation, the healthcare company has devoted decades of research and development to delivering products and solutions to people with skin conditions.

LEO Pharma is headquartered in Denmark and employs close to 4,800 people worldwide.

Read more about LEO Pharma at [www.leo-pharma.com](http://www.leo-pharma.com)

This Environment, Health, Safety and Energy report covers the six LEO Pharma manufacturing sites:

Ballerup, Denmark (headquarters)  
Esbjerg, Denmark  
Cork, Ireland  
Dublin, Ireland  
Vernouillet, France  
Southport, Australia

*“This Environment, Health, Safety and Energy report covers the six LEO Pharma manufacturing sites.”*

## Manufacturing site descriptions

### BALLERUP, DENMARK

The history of LEO Pharma dates back to 1620 where the LEO Pharmacy in Copenhagen became royally privileged.

In 1908, the pharmacists August Kongsted and Anton Antons bought the LEO Pharmacy in Copenhagen. The same year, they founded Løvens kemiske Fabrik in the basement of the pharmacy. The factory expanded quickly and was moved to Brønshøj.

The first production in Ballerup (17 km northwest of Copenhagen) began in 1946 and in 1958 all activities were gathered there after relocation from the previous site in Brønshøj.

During the years, many companies have shown an interest in merging with or acquiring the successful company but Løvens kemiske Fabrik has never returned the interest, and in 1984 Knud Abildgaard created the LEO Foundation to ensure the development of Løvens kemiske

Fabrik as an independent research-based pharmaceutical company. Thus, the LEO Foundation owns all shares in LEO Pharma.

In 2002, Løvens kemiske Fabrik changed its name to LEO Pharma.

The Ballerup site today has multiple corporate functions as well as API and Finished Goods Production. Most of the discovery, research and development departments are also located here.

The production on site can be divided into three main areas: Organic synthesis of active ingredients (vitamin D analogues), biological production of active ingredients (Fucidin®) and finished goods production. Finally, the company runs a secondary activity consisting of a small enzyme production.

## CONTACT

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Organic synthesis requires several synthesis steps and between the individual synthesis steps, it may be necessary to purify the intermediates. For both synthesis and purification, various kinds of organic solvents are used.

In the biological production, the active ingredients are produced from fungi. In many ways, this process is similar to the process of brewing beer.

The production takes place in large tanks with water and culture media consisting of sugar and nutrient salts. When the fermentation is completed, the active ingredient is filtered out and the ingredient is purified a number of times. Organic solvents are used for the purification process.

The finished goods production manufactures and/or packs tablets, capsules, liquid products and sterile products e.g. for injection. As finished goods often only require small amounts of active ingredients these ingredients must be mixed with substances whose only purpose is to function as fillers, carrying medium or flavour additive.

The following drugs are manufactured in Ballerup:

Centyl® K mite, Centyl® K, Daivonex®/Dovonex® Scalp solution, Etalpa®/One-Alpha®, various products containing Fucidin® including Fucithalamic®, Heparin LEO and innohep®, Kaleorid® and Daivobet® and Xamiol®/Taclonex Scalp®. The drugs are all for human use.

Daivonex®/Dovonex®, Daivobet® and Xamiol®/Taclonex Scalp® are used against psoriasis, Etalpa®/One-Alpha against calcium metabolism disorders and various Fucidin® products against infectious diseases.

The site area in Ballerup has grown over the years. Today the total site area is approximately 150,000 m<sup>2</sup>.

The Ballerup site is situated in an area zoned for commercial use and for larger manufacturing enterprises. The Ballerup site holds an IPPC (Integrated Pollution Prevention Control) licence from the Danish Environmental Protection Agency (EPA).

In 2013, the number of employees in LEO Pharma Ballerup equalled 1,538.7 full time employees.

**ESBJERG, DENMARK**

The production in LEO Pharma A/S Esbjerg began in 1976 and the site area is about 34,000m<sup>2</sup>. The Esbjerg site is situated in an area for enterprises with special requirements (heavy industry area) in the southern part of Jutland. LEO Pharma is one of the top manufacturers of the anticoagulant substance heparin, and Esbjerg is where crude heparin is manufactured.

The production site holds an IPPC licence from the Danish EPA. In February 2013, the existing licence was re-

placed with a new license to process 120,000 tonnes mucosa.

When the crude heparin has been extracted from mucosa and bound on an ion exchanger, the crude heparin is shipped to LEO Pharma Cork in Ireland for further treatment.

In 2013, the number of employees in LEO Pharma A/S Esbjerg equalled 10.3 full time employees.



**VERNOUILLET, FRANCE**

The Vernouillet factory was built in 1964 and further expansion has come through the years. The latest expansion was carried out in 2012. The total site area is approximately 56,000 m<sup>2</sup>.

The Vernouillet Finished Goods Manufacturing site is located in the so-called Beauce plain about 80 km west of Paris. This is where active pharmaceutical ingredients (e.g. tinzaparin and fusidic acid) are received from LEO Pharma Cork and LEO Pharma Ballerup respectively, and further processed to pre-filled innohep® syringes and Fucidin® tablets. Burinex® tablets are also manufactured.

In the process, the active pharmaceutical ingredients are mixed with excipients and filling agents and the finished goods are filled into syringes or made into tablets.

Syringes are produced in two ways:

1. One method is where syringes are supplied from external suppliers. LEO then adds the API to the syringes and performs the control and packing.
2. Another method is production of syringes from the start of assembling the syringe to filling in the API and subsequent control and packing. This is called Bulk Manufacturing.

In addition to syringes, the site produces Fucidin® tablets and Burinex® tablets in various doses.

In 2013, the number of employees in Vernouillet equalled 345 full time employees.



**DUBLIN, IRELAND**

The LEO Pharma Finished Goods Manufacturing Ireland site is located near the centre of Dublin in close proximity to both residential and light industrial activities. The original building was constructed in 1954 and in 1960 LEO Pharma took ownership of it and commenced the manufacturing of pharmaceutical products there. From that time various adjacent land acquisitions have been made bringing the total site area up to 42,000m<sup>2</sup>.

The site has been used to manufacture many types of pharmaceutical products over the years including Active Pharmaceutical Ingredients (APIs). However, the manufacture of APIs ceased on site in 2007 and since these “licenced activities” are no longer carried out, the site surrendered its IPPC (Integrated Pollution Prevention Control) licence to the Irish EPA at the end of 2011.

Manufacture on the site is now dedicated to the formulation, filling and packaging of LEO Pharma dermatology products for topical use such as ointments, creams and gels in different formats, but mainly tubes. Product

ranges manufactured include Daivobet®, Dovonex®, Fucidin®, Xamiol® and Picato®. It is also a site for introduction of new topical products and topical applications/solutions, from pilot scale to full scale commercial manufacture.

The bulk manufacturing facility has mixing and homogenising plants in clean rooms with batch volume capacity ranging from 10 litres to 4 m<sup>3</sup> along with all the associated support systems. Filling of the finished product is also carried out in clean rooms. There are a total of seven tube filling and packing lines, one bottle filling line and one web process (bandage) line. There is also a sterile plant within the facility which is dedicated to the production of an ophthalmic eye gel product. This sterile plant also has a dedicated tube filling line.

In 2013, the number of employees in LEO Pharma Dublin equalled 381.2 full time employees.

**CORK, IRELAND**

LEO Pharma Cork is situated in Cork Harbour. In LEO Pharma Cork, two active pharmaceutical ingredients are produced from resin with heparin – Heparin Sodium and Tinzaparin sodium.

The production in Cork began in 1987, and the site area is 79,000 m<sup>2</sup>. The site has production of active pharmaceutical ingredients for Heparin® LEO and innohep®. The site also has different support functions including a development department.

The active pharmaceutical ingredients are shipped to LEO Pharma A/S in Ballerup in Denmark or Vernouillet in France, where the heparin or tinzaparin finished products are manufactured. The trading name for tinzaparin is innohep®. innohep® is an anticoagulant and is used for prevention and treatment of blood clots.

In 2013, the number of employees in LEO Pharma Cork equalled 52.5 full time employees.



**PEPLIN OPERATIONS, API SOUTHPORT, AUSTRALIA**

LEO Pharma's manufacturing site in Australia is situated in Southport in Queensland and is referred to as Peplin Operations or API Southport.

Peplin Operations PTY LTD (Peplin Operations) was acquired by LEO Pharma in November 2009. Peplin Operations' main function is to manufacture an Active Pharmaceutical Ingredient (API) from a plant called Euphorbia Peplus (E-Peplus or PEP005) which contains ingenol mebutate for Picato®.

In 2012-2013, Peplin Operations completed an upgrade of the manufacturing facility to support the transition from an R&D facility in 2011 to a full scale production plant facility in 2013. Since the upgrade, Peplin Operations has become a more lean and efficient site.

The process commences with the delivery of fresh E-Peplus plants to the site. Then the plants go through a number of manufacturing process steps including drying and milling, extraction, purification and quality control. The final manufacturing process of the active pharmaceutical ingredient is purification where it is crystallized, then packed and shipped overseas to their final destination in Dublin and a contract manufacturer in the USA. This forms the finished product – Picato® which is used to treat Actinic Keratosis, a precancerous skin condition caused by sun damage.

In 2013, the number of employees in Peplin Operations equalled 50.6 full time employees.



## Environment, Health, Safety and Energy policies

At LEO Pharma, global policies concerning environmental affairs, energy performance and occupational health and safety are as follows:

### LEO Pharma Corporate Environment and Energy Policy

**LEO Pharma is committed to the protection of the environment, the prevention of pollution and the continual improvement in energy performance.**

**LEO employees follow applicable environmental laws, regulations and policies.**

**We conduct business in a manner that protects the environment.**

**We strive to develop a proactive, continuous improvement working culture in which good environment practice is a natural part.**

**To demonstrate this commitment, LEO Pharma will:**

1. Comply with all applicable legislation, regulations and obligations related to environmental performance and energy consumption, efficiency and performance.
2. Provide necessary human and financial resources to ensure that this policy is implemented and maintained and objectives and targets are achieved.
3. At our manufacturing sites we will:
  - Implement an Environment and Energy Management System in accordance with ISO international standards in order to continuously reduce our environmental impact.
  - Define specific environmental and energy goals and make all employees aware of these goals.
  - Ensure that all new projects are designed and built using best available technology for environmental and energy performance

LEO Pharma will communicate this policy to all persons working for LEO and ensure that it is available to the public.

In order to ensure that this policy is effectively implemented and managed, it will be reviewed annually and updated where and when required.



Anders B. Spohr  
Executive Vice President  
24 September 2012



Gitte Aabo  
President & CEO  
24 September 2012

### LEO Pharma Corporate Health and Safety Policy

**LEO Pharma provides a safe and healthy working environment for all employees, contractors and visitors. LEO Pharma takes measures against Occupational Health and Safety problems in a professional and effective manner.**

**LEO employees follow applicable health and safety laws, regulations and policies. We conduct business in a manner that protects the health and safety at our workplace.**

**We strive to develop a proactive, continuous improvement working culture in which good health and safety practice is a natural part.**

**To demonstrate this commitment, LEO Pharma will:**

1. Comply with current legislation on occupational health and safety (OHS) and any agreements made with organisations regarding OHS requirements.
2. Provide necessary human and financial resources to ensure that this policy is implemented and maintained and objectives and targets are achieved.
3. At our manufacturing sites we will:
  - Implement an Occupational Health and Safety Management System in accordance with OHSAS international standards and continuously improve our health and safety performance.
  - Define specific health and safety goals and make all employees aware of these goals.

LEO Pharma will communicate this policy to all persons working for LEO and ensure that it is available to the public.

In order to ensure that this policy is effectively implemented and managed, it will be reviewed annually and updated where and when required.



Anders B. Spohr  
Executive Vice President  
24 September 2012



Gitte Aabo  
President & CEO  
24 September 2012



## Environment, Health, Safety and Energy Goals

As a consequence of these policies, the following long term goals were set in 2011 by Group Management.

### ENVIRONMENT AND ENERGY GOALS

LEO Pharma has the following global goals on environmental affairs and energy:

1. All existing manufacturing sites must be ISO14001 certified by the end of 2015
2. At the end of 2015, energy projects with a total saving of 15% of the energy consumed in 2010 will be implemented (equal to about 20,000 MWh).

#### Explanation of the energy goal:

If nothing changes (i.e. the activities at our manufacturing sites is the same as in 2010), the total energy consumption in 2015 will be max 85% of the 2010 consumption. However, the total energy consumption in 2015 may be higher if production rises, expands or new facilities are built or taken into use. On the other hand, the total energy consumption may fall if production goes down, part of it is outsourced or buildings are taken out of use.

### HEALTH AND SAFETY GOALS

LEO Pharma has the following global goals on health and safety:

1. All existing manufacturing sites must be OHSAS18001 certified by the end of 2015
2. The group LTI rate is on par with the best in industry at the end of 2015.

Explanation to the LTI rate goal:

LTI rate is calculated as:

$$LTI\ rate = \frac{(\text{number of injuries with absence} * 1000000\ \text{working hours})}{\text{Total number of working hours}}$$

The injuries included in this calculation are injuries with absence beyond the day of the injury (note: other companies include only the injuries with more than three days of absence from work).

### STATUS ON 2015 GOALS

In 2013, the manufacturing sites have been working on both the management system certification goals as well as the goals related to energy and occupational injuries.

Not all of the goals have been achieved yet, but we are confident that they will be achieved before the end of year 2015.

### MANAGEMENT SYSTEMS CERTIFICATION GOALS

The status and plans of the goals related to management systems are as follows:

	OCCUPATIONAL HEALTH AND SAFETY	ENVIRONMENTAL AFFAIRS
	OHSAS 18001	ISO 14001
<b>Ballerup</b>	Re-certified in 2013	System in place 2013
<b>Esbjerg</b>	Re-certified in 2013	System in place 2013
<b>Vernouillet</b>	Scheduled for 2014	Certified in 2011
<b>Cork</b>	Certified in 2013	Scheduled for 2014
<b>Dublin</b>	Scheduled for 2013	Certified in 2012
<b>Southport</b>	Scheduled for 2015	Scheduled for 2015

In the beginning of the year, LEO Pharma Cork received the OHSAS 18001 certificate. LEO Pharma Ballerup and Esbjerg were also re-certified and every effort must be made to repeat the good work in 2014.

In 2013, the environment, health and safety (EHS) team in Denmark has been working hard to integrate the existing health and safety management system to also include environment and to get it ready for ISO 14001 certification. EHS Denmark had a successful pre-certification audit in October which will be followed by the certification audit in February 2014.

Cork has had some challenges as a result of staff reduction and might not reach ISO 14001 certification in 2014 as scheduled but will have the management system in place.

Dublin received ISO 14001 certification in 2012, and successfully completed a surveillance audit in 2013 to retain certification. The site also retained certification to Energy Management System ISO 50001 in 2013.

An OHSAS 18001 certification audit of the Dublin site took place in late December. The site did not reach immediate certification to this standard, and certification will be subject to satisfactory closure of findings, which will be evaluated in a follow-up audit in 2014.

LEO Pharma in Vernouillet and Southport are on track and are expected to reach their certification goals.

### ENERGY GOAL

The purpose is:

- To build and execute efficient systems regarding energy savings in Global Product Supply (GPS) and R&D by the end of 2015
- To evaluate effective and coherent energy solutions across production sites to reduce our carbon emissions
- To establish a common understanding of where to invest in energy effective solutions in order to maximise return on investment

The status, as of today, is that energy saving projects implemented since 2011 has resulted in a total saving of 24,173 MWh. The 2015 goal was already reached in 2012, but new energy saving projects will still be implemented each year.

Further information concerning the projects carried out can be seen in the section on energy performance.

### LOST TIME INJURY RATE GOAL

The work to reach a group LTI on par with the best in industry at the end of 2015 is on-going. To achieve this goal, we increased our focus on Safety Awareness in 2013 and we will continue this focus in the years to come.

Our goal for 2013 was an LTI rate of 4.4 but we ended up with a total LTI rate of 6.5.

Find more information on LTI is found under "Health and Safety Management".

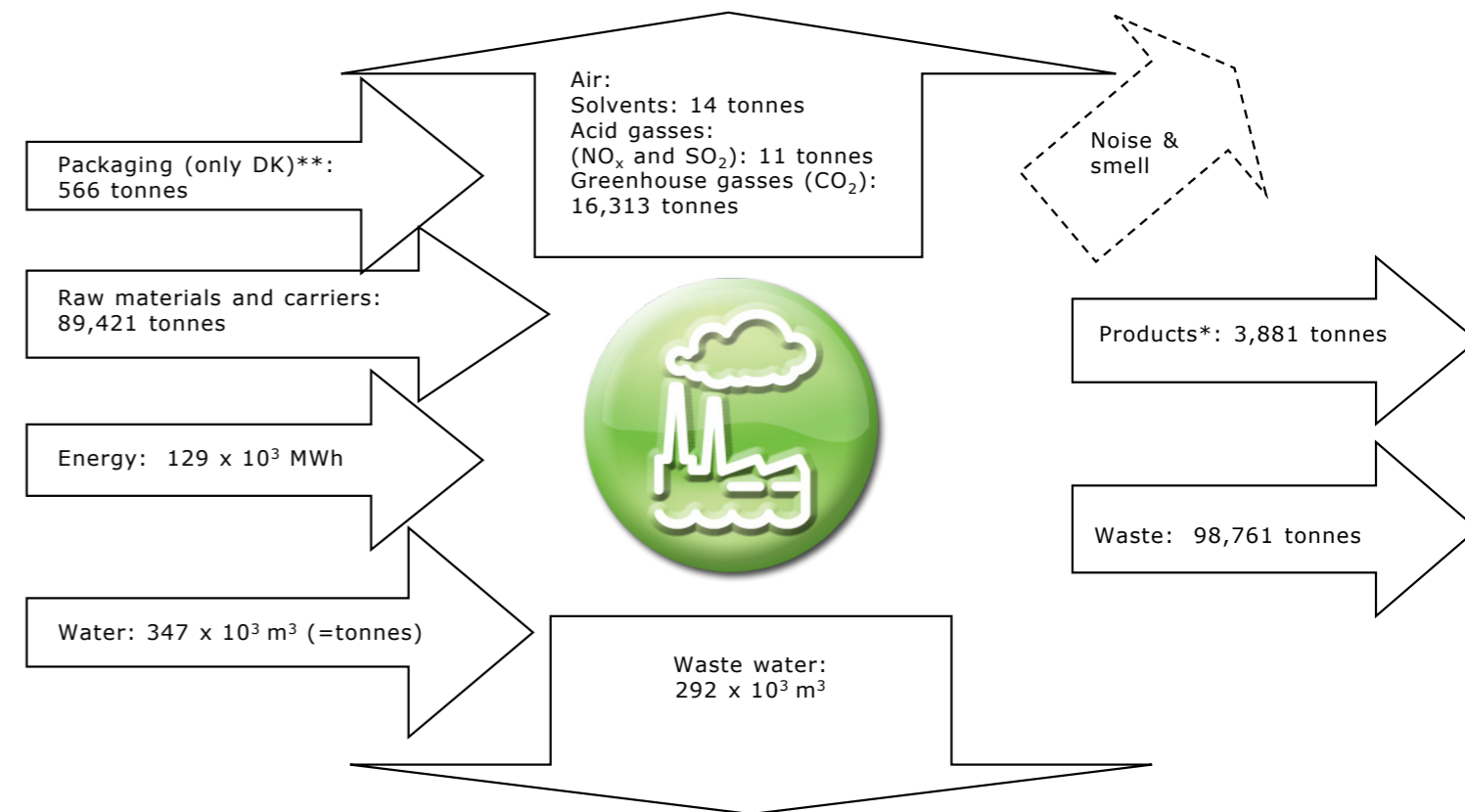


## LEO Production and Environmental aspects

### ENVIRONMENTAL PERFORMANCE

The production takes place at six different sites and consists of various unit operations and syntheses and the environmental performance of each site is described later in this chapter. The following figure shows the overall environmental performance across all sites.

The overall LEO Pharma performance in 2013:



\*Products incl. packaging (and intermediates sent for further processing at other plants)  
 \*\*Packaging as input only covers the packaging materials used in DK in 2013

# Input

## RAW MATERIAL AND CARRIERS

The company's consumption of raw materials and carriers can be divided into the following categories (rounded off to whole tonnes):

Raw materials and carriers	2010	2011	2012	2013
Organic solvents	1,247	1,633	2,064	1,531
Pharmaceutical products	34	41	40	38
Agricultural products	61,937	75,968	82,400	80,748
Acids/bases	331	469	370	383
Gels and filter material	1	50	20	19
Other organic compounds	1,274	1,313	1,294	1,226
Inorganic substances	4,604	5,485	5,322	5,444
Detergents	20	21	21	32
<b>TOTAL</b>	<b>69,448</b>	<b>84,980</b>	<b>91,531</b>	<b>89,421</b>

Some of the pharmaceutical products used as raw materials are products from other LEO Pharma manufacturing sites.

The decline in the production of Fucidin® results in reduced use of solvents at the manufacturing site in Ballerup. In Cork, there has also been a decline in the production of Heparin and Tinzaparin contributing to the reduction in use of organic solvents.

Raw materials included in the grouping "agricultural products" are, amongst others, intestinal mucosa, sugar, corn-steep and E. Peplus plants. Mucosa is a waste product from abattoirs and contains the important polysaccharide, heparin. E. Peplus is the plant from which the raw material for ingenol mebutate is extracted.

The consumption has dropped from 2012 to 2013 because of decreased use of mucosa for crude heparin and corn steep and sugar for fusidic acid production.

The grouping "inorganic substances" covers *inter alia* use of salt which has gone up as a result of increased water purifying processes.

Increased use of detergents is due to new production facilities in Dublin and Vernouillet.

## ENERGY

LEO Pharma has completed energy saving projects that will result in energy savings of 24,173 MWh per year. The projects have been implemented over the last three years. The energy consumption at the Dublin site has risen due to increased production of finished goods. The energy consumption has fallen in Ballerup due to a lower production of API and finished goods.

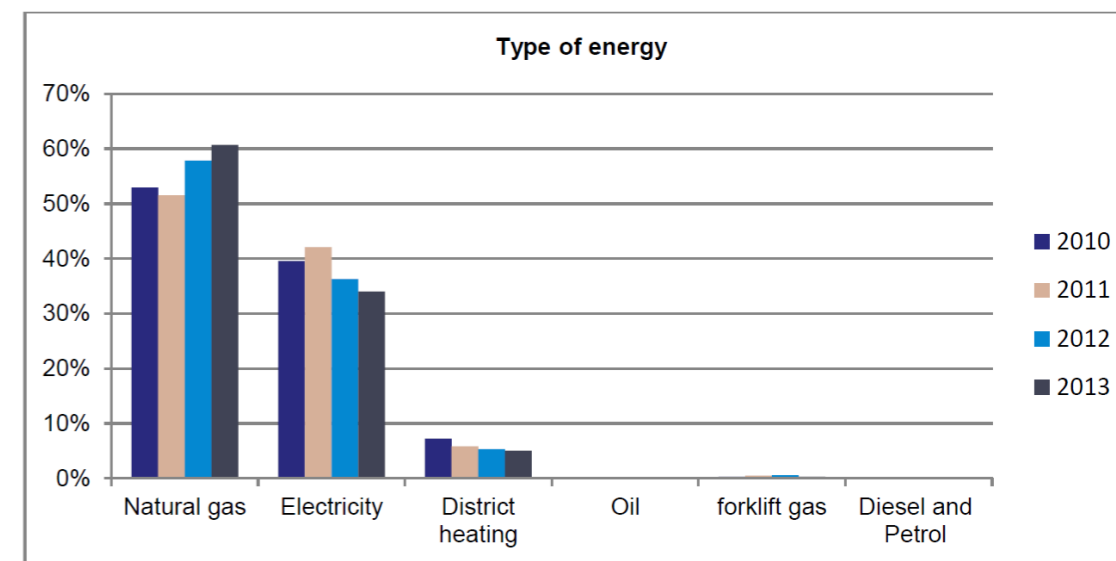
The LEO Pharma 2015 energy goal has been achieved, but the energy saving projects will continue as energy projects make good business sense.

The consumption of energy in 2013 corresponded to the energy consumption (light, heating, cooking etc.) of 6,689 average single family households (Danish key figure).

Total consumption of energy over the last four years has been:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	MWh	76,764	71,030	70,172	66,898
DK - Esbjerg	MWh	7,098	8,225	8,337	6,236
FR - Vernouillet	MWh	14,280	15,862	17,812	16,786
IE - Cork	MWh	6,728	6,275	6,664	6,917
IE - Dublin	MWh	23,002	23,386	28,175	30,260
AUS - Southport	MWh	917	1,215	1,904	1,608
<b>TOTAL</b>	<b>MWH</b>	<b>128,789</b>	<b>125,993</b>	<b>133,064</b>	<b>128,705</b>

The energy consumed, divided into the different types being used at LEO Pharma:



## Energy performance and projects in 2013

### Ballerup

In 2013 only minor projects in part of R&D were implemented. This was regarding alarms and the amount of air sucked out of the fume hoods. These projects resulted in energy savings of 180 MWh of which 33 MWh was electricity and 147 MWh was natural gas. Preliminary work has been conducted on 5 projects, which will be implemented later.

### Esbjerg

The consumption of energy at the Esbjerg site has reduced significantly (by ~25%). The main reason is that an extra and unnecessary hygienisation step was discontinued in August 2012 as it showed no effect on the hygiene of the residue product (the fertilizer Fertigro®).

### Vernouillet

In 2013, three energy optimisation projects were identified and implemented with payback time lower than three years. The projects were: new modulating burners on the boilers, regulation of condensing on the boilers and speed variation of the pump on the chilled water network.

Furthermore, old fluorescent tubes in a production workshop were replaced by LED tubes. The result was a major decrease in electricity consumption. As a consequence of this excellent result, the LED technology will be implemented in others areas of production in the years to come.

### Cork

In 2013, a project was undertaken to replace administration and canteen area lighting with high efficiency long life LED lighting which has ~45% energy saving, ~57% CO2 emission saving and six time longer operating life thereby saving on maintenance costs as well.

In 2013, 6.3% less product was produced than in 2012 with a 1.5% rise in energy usage. The main contribution to this is attributed to higher ventilation costs due to an unusually warm summer which required more energy usage for cooling and humidity control in controlled production areas.

### Dublin

A number of significant energy saving initiatives has taken place through the year, generating an annual energy saving of 480 MWh and cost saving of €68,000. These energy optimising projects included replacement of inefficient machinery, changes to air conditioning, heat tracing and lighting.

The 'quad-gen' CHP (Combined Heat and Power Plant) project which was completed in 2012 continues to provide benefits with the near elimination of the need to purchase electricity from the utility companies. Electricity generated on-site provides virtually all the site's electrical, heating and chilling requirements. This project was submitted to the Pharmachem Ireland Responsible Care Awards and, although it didn't win, it was highly commended by the judges.

### Southport

In Southport, the energy consumption has been significantly smaller in 2013 compared to 2012. This is caused by the production volume in Southport being lower in 2013 than 2012. The main energy consumers in Southport are the dryers.

A hard pipe supply of natural gas has been introduced into the facility and the LPG gas bottles will then be eliminated in the drying process.

## WATER

LEO Pharma uses water for production processes, in the composition of products and for cleaning and sanitary purposes. All water comes from a municipal water supply.

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	m <sup>3</sup>	165,622	152,898	150,106	174,454
DK - Esbjerg	m <sup>3</sup>	16,220	21,954	25,266	22,589
FR - Vernouillet	m <sup>3</sup>	21,653	20,507	26,094	36,719
IE - Cork	m <sup>3</sup>	41,922	35,406	47,266	55,114
IE - Dublin	m <sup>3</sup>	43,416	41,692	49,746	53,890
AUS - Southport*	m <sup>3</sup>	1,308	1,308	2,554	4,186
<b>TOTAL</b>	<b>M<sup>3</sup></b>	<b>290,141</b>	<b>273,765</b>	<b>301,032</b>	<b>346,952</b>

\*Water consumption for Southport in 2010 was unknown and was set as equal to 2011.

The total consumption of water in 2013 corresponded to the consumption of 2,884 average single family households (Danish key figures).

### Ballerup

We have seen an increased use of water in 2013 in Ballerup. The main reason is that large amounts of condensate for the boilers have been exchanged because of contamination and have thus not been reusable. Other reasons are increased validation activities in the Fucidin® area as well as usage of water in a rented building across the street of LEO Pharma.

### Esbjerg

The decline in use of water in Esbjerg from 2012 to 2013 was due to the new production facility which came into use in spring 2012 and the subsequent close down of the activities in the old factory.

### Vernouillet

The increased water consumption in Vernouillet was caused by installation of a new purified water loop in 2013. The validation period was very long, which required approximately 7000 m<sup>3</sup> of water. It was also

caused by implementation of dehumidifiers on Air Handling System's new building, which resulted in increased consumption of about 970 m<sup>3</sup> of water from 2012 to 2013. Other changes in operations also contributed to the increase.

### Cork

The increase in water consumption in Cork was mainly due to increased washing of resin due to higher phosphorus levels in incoming raw material.

### Dublin

The increased consumption at the Dublin site in 2013 was due to the installation and commissioning of the new purified water plant. This plant had to be run for an extended period while qualification and validation work was taking place and the water produced in that period is not suitable for use in production.

### Southport

The increased use of water in Southport was due to changes in the production methods of ingenol mebutate for Picato®.



# Output

## PRODUCTS

LEO Pharma production divided into the six manufacturing sites:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	1,825	1,640	1,630	1,259
DK - Esbjerg	tonnes	8	10	11	11
FR - Vernouillet	tonnes	54	60	90	92
IE - Cork	tonnes	11	15	16	15
IE - Dublin	tonnes	2,650	2,655	2,378	2,504
AUS - Southport	tonnes	*	*	*	*
<b>TOTAL</b>	<b>TONNES</b>	<b>4,548</b>	<b>4,380</b>	<b>4,125</b>	<b>3,881</b>

\*Means production amount is confidential.  
The production volume includes packaging.

Most of the production in Ballerup is finished goods. The decrease is a result of general decrease of finished goods production in Ballerup as some of the products are produced in smaller quantities for sale or part of the production has been moved to other sites or contract manufacturers.

The production volume from Esbjerg is intermediate for the Cork site. Cork only produces intermediates for Vernouillet and Ballerup. All products from Vernouillet and Dublin are finished goods. Southport only produces intermediates for Dublin and a contract manufacturer in the USA.

## WASTE

The total amount of waste generated by LEO Pharma:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	2,612	2,718	2,567	2,326
DK - Esbjerg	tonnes	67,905	83,981	93,806	94,149
FR - Vernouillet	tonnes	397	521	588	581
IE - Cork	tonnes	304	678	144	151
IE - Dublin	tonnes	708	692	697	743
AUS - Southport	tonnes	37	37	1,836	811
<b>TOTAL*</b>	<b>TONNES</b>	<b>71,963</b>	<b>88,627</b>	<b>99,638</b>	<b>98,761</b>

\*Construction and project related waste is excluded.

The rise in waste in Dublin is related to increased production and waste associated with trials in relation to new products being introduced on site.

In Southport focus has been on waste streams and some waste reducing initiatives have been introduced to minimise the carbon footprint on the environment due to less transportation of liquid waste from the production process. One of the projects has resulted in a nearly 40% reduction of waste produced per batch.

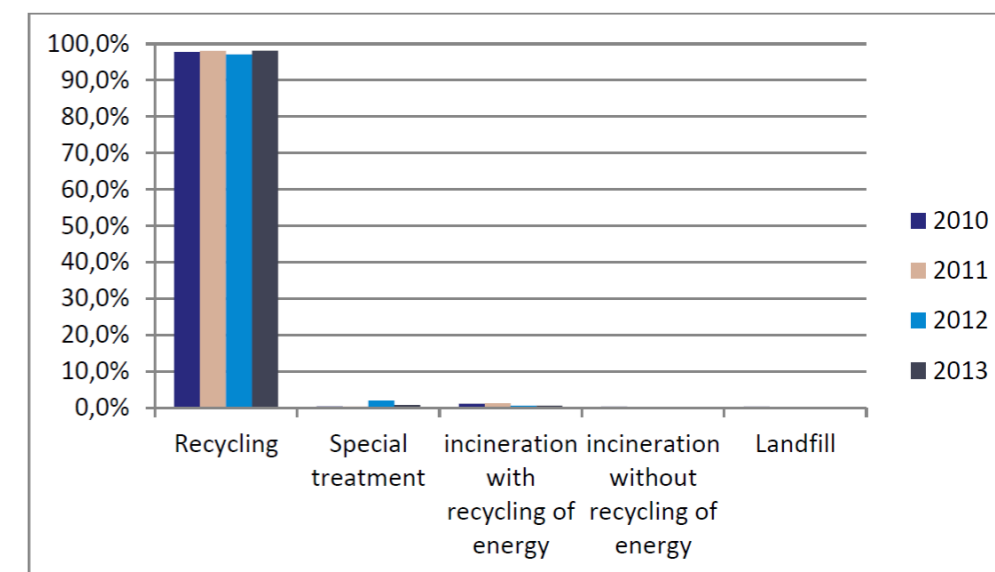
In Southport, the residue weed and the water from the extraction process are now removed offsite by a certified waste contractor and reused as fertilizer and water supply to green fields. So instead of the weed being sent to land fill, it is now recycled as fertilizer.

However, most of the waste from LEO Pharma comes from the Esbjerg site and consists of intestinal mucosa from which the heparin is extracted.

The Esbjerg site extracts the polysaccharide heparin from intestinal mucosa from pigs. The concentration of heparin in mucosa is low which means that an input of approximately 70,000 tonnes mucosa results in approximately 10 tonnes of extracted crude heparin. The large amounts of residue product are primarily recycled as farm land fertilizer (under the trade name Fertigro®) and secondarily as an energy source in biogas producing plants.

Consequently, the recycling percentage is high, as the following chart shows.

Waste divided into kinds of treatment:



Waste for recycling (recycle or reuse), besides mucosa waste, consists of: cardboard, paper, glass (clear and coloured), plastic (soft and hard), iron, aluminium, stainless steel, cable scrap, electronic scrap, fluorescent tubes and batteries.

Other kinds of waste that we sort out for different kinds of treatment or re-use are: combustible waste, construction waste for recycling, waste deposit and incineration, pharmaceutical waste, clinical risk waste, chemical waste for recycling, chemical waste for special treatment, and PVC.

The reason why LEO Pharma sorts so many different fractions is that – for some fractions – it is a local legal requirement. Other fractions are sorted out because there is a financial benefit in sorting out the fraction.

On a regular basis, LEO Pharma investigates the options for implementing additional sorting or minimising waste generation.

**WASTE WATER**

Waste water is water from the production, cleaning and sanitary waste water. The waste water is sent to municipal treatment for purification before it is led out to the sea or river.

Amounts of waste water being discharged:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	m <sup>3</sup>	158,246	145,315	138,000	153,816
DK - Esbjerg	m <sup>3</sup>	5,190	7,025	9,231	10,167
FR - Vernouillet	m <sup>3</sup>	16,596	15,906	19,713	44,718
IE - Cork	m <sup>3</sup>	19,077	18,042	28,845	35,119
IE - Dublin	m <sup>3</sup>	37,756	45,759	45,544	47,524
AUS - Southport	m <sup>3</sup>	N/A	N/A	N/A	622
<b>TOTAL*</b>	<b>M<sup>3</sup></b>	<b>236,865</b>	<b>232,047</b>	<b>241,333</b>	<b>291,966</b>

\*Only sanitary waste is led to the sewage. The amount is not measured.

The overall Chemical Oxygen Demand (COD) from the different sites:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	363	385	290	349
DK - Esbjerg	tonnes	4	5	43	76
FR - Vernouillet	tonnes	2	2	1	6
IE - Cork	tonnes	4	5	5	9
IE - Dublin	tonnes	15	18	16	19
AUS - Southport	tonnes	N/A	N/A	N/A	N/A
<b>TOTAL</b>	<b>TONNES</b>	<b>388</b>	<b>415</b>	<b>355</b>	<b>459</b>

The major COD from the waste water effluent in Ballerup stems from the production of Fucidin® API.

From the Esbjerg site there has been an increased amount of COD in the waste water due to the activities in the new production area. The waste water contains residues of mucosa which is easily biodegradable in the waste water treatment plant. The municipal waste water treatment plant is located next door to LEO Pharma Esbjerg.

The measurements of COD in the waste water from the

site in Vernouillet show considerably increased concentrations. The reason is a change in the method of collecting and analysing the waste water. The changes have been made to display a more representative image of the activities on site.

There has been an increase of COD in the waste water from Cork due to increased washing of raw material. This washing is due to higher phosphorus levels in the raw material. The washing water is sent to effluent which is the reason for the increased waste water discharged from the site.

**AIR EMISSIONS**

The activities of the company resulted in a number of solvents, acid gases and greenhouse gases being emitted into the air.

Emission of organic solvents to the atmosphere from the production:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	9.5	13.7	11.6	11.4
DK - Esbjerg	tonnes	0	0	0	0
FR - Vernouillet	tonnes	0.6	0.2	1.5n/a	1.8
IE - Cork	tonnes	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	n/a	n/a	n/a	n/a
AUS - Southport	tonnes	n/a	n/a	0.2	0.6
<b>TOTAL</b>	<b>TONNES</b>	<b>10.1</b>	<b>13.9</b>	<b>13.3</b>	<b>13.8</b>

The majority of emitted solvents are: from the biological production and purification; and from the organic synthesis - both in Ballerup.

The emission of the greenhouse gas carbon dioxide (CO<sub>2</sub>) on site:

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	7,078	6,331	6,342	6,128
DK - Esbjerg	tonnes	1,319	1,531	1,492	1,107
FR - Vernouillet	tonnes	1,501	1,444	2,019	2,500
IE - Cork	tonnes	n/a	1	1	1
IE - Dublin	tonnes	2,364	2,816	5,014	6,107
AUS - Southport	tonnes	133	133	146	470
<b>TOTAL</b>	<b>TONNES</b>	<b>12,395</b>	<b>12,256</b>	<b>15,013</b>	<b>16,313</b>

The amount of CO<sub>2</sub> for DK is only from direct emission emitted onsite (e.g. emission from own boilers or forklift gas).

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from [www.key2green.dk](http://www.key2green.dk).

**Emission of NO<sub>x</sub>:**

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	5.5	4.9	4.9	4.7
DK - Esbjerg	tonnes	1.0	1.1	1.1	0.8
FR - Vernouillet	tonnes	1.2	1.2	2.1	0.0
IE - Cork	tonnes	n/a	1.2	1.3	0.4
IE - Dublin	tonnes	4.0	5.0	8.8	4.7
AUS - Southport	tonnes	1	1	0.2	0.4
<b>SUM</b>	<b>TONNES</b>	<b>13</b>	<b>14</b>	<b>18</b>	<b>11</b>

The amount of NO<sub>x</sub> is only from direct emission emitted on-site (e.g. emission from own boilers or forklift gas).

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from [www.key2green.dk](http://www.key2green.dk).

In Dublin, the installation of the 'quad-gen' CHP (Combined Heat and Power Plant) has resulted in a lower emission of NO<sub>x</sub>.

**Emission of SO<sub>2</sub>:**

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	0.04	0.04	0.04	0.03
DK - Esbjerg	tonnes	0.01	0.01	0.01	0.01
FR - Vernouillet	tonnes	0	0	0.02	0.02
IE - Cork	tonnes	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	n/a	n/a	n/a	0.09
AUS - Southport	tonnes	~0	~0	~0	0.08
<b>SUM</b>	<b>TONNES</b>	<b>0.05</b>	<b>0.05</b>	<b>0.07</b>	<b>0.23</b>

The amount of SO<sub>2</sub> is only from direct emission emitted on-site (e.g. emission from own boilers or forklift gas).

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from [www.key2green.dk](http://www.key2green.dk).

**Emission of ozone-depleting substances (ODS) (CFC, HCFC, halon and methyl bromide):**

Site	UNIT	2010	2011	2012	2013
DK - Ballerup	tonnes	0	0.069	0.06	0.105
DK - Esbjerg	tonnes	0	0	0	0
FR - Vernouillet	tonnes	0	0	0.015	0
IE - Cork	tonnes	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	0.067	0.175	0.0125	0.0503
AUS - Southport	tonnes	n/a	n/a	n/a	n/a
<b>TOTAL</b>	<b>TONNES</b>	<b>0.067</b>	<b>0.244</b>	<b>0.0875</b>	<b>0.1553</b>

In Ballerup, HCFC was used for topping up the old cooling system.

is not possible investigations are made to determine whether the ground contamination has caused any contamination of the groundwater, and whether the contamination is within company premises. If not, counter-pumping is initiated.

**GROUND AND GROUNDWATER PROTECTION**

Today, the company prevents contamination of ground and groundwater by handling chemical substances and products in such a way that the risk of spills and environmental incidents is minimised.

If the contamination is within our own area, the groundwater is monitored in order to discover any possible development.

If possible, it is LEO Pharma's policy to seal or remove existing ground contamination by excavation. If this

A prerequisite for the above is that the contamination is caused by the company itself.



**ENVIRONMENTAL ACCIDENTS/INCIDENTS**

The number of environmental accidents/incidents reported to the authorities:

Site	2010	2011	2012	2013
DK - Ballerup	2	3	3	18
DK - Esbjerg	0	0	2	0
FR - Vernouillet	0	0	0	3
IE - Cork	10	15	5	10
IE - Dublin	2	2	2	6
AUS - Southport	0	0	0	1
<b>TOTAL</b>	<b>14</b>	<b>20</b>	<b>12</b>	<b>38</b>

**Ballerup:**

There have been two major environmental incidents in Ballerup in 2013 and 16 minor incidents. The major incidents were a spill of approx. 200 litres of hydraulic oil into the sewer and an unintended release of Fucidin® on the roof of one of the buildings. One of the minor incidents was a small spill of toluene due an open bottom valve where the toluene was collected in a gas trap which was emptied afterwards.

The remaining 15 incidents have all been related to waste water and noncompliance with the waste water permit. The major part of the incidents was caused by COD/BOD above permitted level due to very low organic concentration in the waste water. Other incidents were caused by inhibition of the nitrification, too much suspended solids, chloride, sulphate or oil in the waste water.

To avoid so many incidents with noncompliance with the waste water permit, a goal has been set for 2014 where the reasons will be investigated by employees from the EHS department who will follow parts of the production to find reasons for these the incidents.

**Vernouillet:**

One of the incidents has been more discharged water than permitted in the waste water discharge permit and two of the incidents have been too high pH level in the discharged waste water.

**Cork:**

Two incidents were surface water COD exceeding permitted levels. Another incident was suspended solids exceeding permitted levels. Four incidents were effluent phosphorus exceeding permitted levels. There was one incident of effluent volume exceeding the daily discharge limit and finally there were two incidents of surface water conductivity exceeding permitted levels. None of the environmental incidents has caused damage to the environment and all were categorised as minor/no impact by the EPA.

**Dublin:** There were six incidents notified to the licensing authorities, Dublin County Council, in 2013. Two were COD exceeding limits, and two were where process water went to foul drains. None of the incidents caused damage to the environment.

**Southport:** In connection with replacement of an old waste tank, a crack was found in the pipe of the old tank leaking dirty water to the ground. No dirty water reached the water table or storm water. The ground soil was removed when the new tank was inserted.

**COMPLAINTS**

LEO Pharma received complaints:

Site	2010	2011	2012	2013
DK - Ballerup	0	1	1	0
DK - Esbjerg	0	0	0	0
FR - Vernouillet	0	0	0	0
IE - Cork	0	0	0	0
IE - Dublin	0	2	0	2
AUS - Southport	0	0	0	0
<b>TOTAL</b>	<b>0</b>	<b>3</b>	<b>1</b>	<b>2</b>

The complaints received in Ballerup in 2011 and 2012 were regarding smell coming from the heating of corn steep. The smell contains no harmful substances and this was explained to the complainant. A project team has been investigating different solutions for reduction of the smell and has now found a solution. The chosen solution is condensation of the air from the sterilisation of corn steep as most of the smell will then be captured in the condensate and released with the waste water. The solution will be implemented on the tanks during 2014.

Dublin received two neighbour complaints in 2013 regarding noise. The reason was a fault in the new aerosol plant which caused the fan to run excessively.

**ENVIRONMENTAL PERMITS AND LICENSES**

LEO Pharma's manufacturing sites have the required environmental permits for their operations and outlets according to local law and the permits and licenses are updated when needed.







## Health and Safety Management

### OCCUPATIONAL INJURIES

The work to reach a group LTI on par with the best in industry at the end of 2015 is on-going. To achieve this goal, LEO Pharma has decided to have extra focus on Safety Awareness in the years to come by providing employees and managers with the tools and information they need in order to take action to invest in their personal health and safety and by working hard to establish a “culture of safety” through additional training and practices.

The number of days lost due to an injury says something

about the severity of the injury. All in all the number of days away from work due to an occupational injury has been much higher in 2013 than in 2012. This is due to more injuries and some of them with longer absence from work.

In the table below the Lost Day Rates for the previous four years are calculated.

According to GRI (Global Reporting Initiative), the Lost Day Rate (LDR) is calculated as:

$$\text{LDR} = \frac{(\text{number of days lost} * 200000)}{\text{total working hours}}$$

### Lost Day Rate (LDR):

Site	LDR			
	2010	2011	2012	2013
DK - Ballerup	21.07	5.86	1.95	5.00
DK - Esbjerg	0.00	0.00	8.58	0.00
FR - Vernouillet	194.63	139.63	48.01	64.14
IE - Cork	0.00	7.60	0.00	0.00
IE - Dublin	83.75	7.33	26.03	29.00
AUS - Southport	0.00	4.98	1.36	10.83
<b>TOTAL</b>	<b>50.10</b>	<b>23.31</b>	<b>11.84</b>	<b>17.40</b>

The number of lost days may not all originate from injuries in the same year as the number of lost days are summarised by calendar year. This means that some lost days may originate from injuries from the previous year, and other lost days may be counted in the year following the injury.

LEO Pharma focuses on bringing down the number of injuries that causes absence beyond the day of the injury. The goal for 2013 was to have fewer injuries with absence than in 2012 and **to reach an LTI rate of 4.4**. As can be seen from the explanations below, this goal was not reached. The number of lost time injuries in 2010-2013 was:

Site	2010	2011	2012	2013
DK - Ballerup	16	16	12	11
DK - Esbjerg	0	0	1	0
FR - Vernouillet	8	8	4	9
IE - Cork	0	1	0	0
IE - Dublin	3	2	4	4
AUS - Southport	0	2	1	2
<b>TOTAL</b>	<b>27</b>	<b>29</b>	<b>22</b>	<b>26</b>

The Lost Time Injuries rate is stated below and is calculated as:

$$\text{LTI rate} = \frac{(\text{number of injuries with absence} * 1000000 \text{ working hours})}{\text{Total number of working hours}}$$

**Lost Time Injury Rate:**

Site	LTI			
	2010	2011	2012	2013
DK - Ballerup	7.0	6.5	4.7	4.3
DK - Esbjerg	0.0	0.0	54.6	0.0
FR - Vernouillet	20.9	16.6	7.7	15.9
IE - Cork	0.00	9.5	0.0	0.0
IE - Dublin	5.1	3.3	6.1	6.0
AUS - Southport	0.00	24.9	9.0	21.7
<b>TOTAL</b>	<b>7.9</b>	<b>7.7</b>	<b>5.5</b>	<b>6.5</b>

**Ballerup and Esbjerg:**

At LEO Pharma we are handling and working with a lot of different chemicals where the health risks have not yet been determined or the chemicals are highly potent. This is especially true for the R&D departments in Ballerup.

In order to improve the occupational health and safety for the employees, it was decided to purchase 22 safety hoods. They have laminar airflow and protect the employees from exposure to particles as the air is sucked out of the bottom of the safety hood. The safety hoods have been installed in various R&D departments and QC labs. Thus the employees will have to do weighing of hazardous, solid chemicals in the safety hoods. Fume cupboards do not offer the same level of protection when handling solids as they are designed for sucking out fumes and do so from the top of the cupboard. The employees have been trained in the use of the safety hoods and a news article with safety points regarding work methods was issued in an EHS newsletter in April 2013.

Other initiatives in Denmark have been the safety awareness campaigns from Global EHS which have been sent

to all the EHS groups monthly and shown on the screens in the staff restaurant. There has also been a meeting in the EHS organisation regarding injuries where the very powerful film “Ken Woodward story” was shown and there was a good discussion about injury prevention afterwards. An outdoor safety inspection has also been completed in 2013.

**Vernouillet:**

One of the objectives in Vernouillet in 2013 was to become closer to the workforce by communicating and informing them better. This was done by starting monthly indicators that everyone could understand and conducting “EHS WALKS” in all departments.

Despite strenuous efforts on the part of EHS, the LTI rate for 2013 is disappointing. There were nine injuries with absence which proves that the safety culture has not been as securely established as expected.

Therefore, the effort will be re-doubled in 2014 to meet the objective that has been set.

Some of the initiatives are to rely heavily on the setting up of departmental co-ordinators attached to EHS and safety awareness training for managers.

**Cork:**

Due to the excellent and diligent work of all onsite, the manufacturing plant in Cork ended the year 2013 with no injuries resulting in more than 1 day of absence.

**Dublin:**

Safety awareness has been increased on the site through a number of initiatives:

GMP and Health & Safety are different sides of the same compliance coin. Both depend on positive behaviours and habits. They go hand-in-hand in safeguarding our licences to operate.

To help foster a general compliance mind-set, it was decided to combine EHS training with the annual GMP training that is mandatory for all in Dublin. This initiative took place over 15 sessions in November and December 2013, and as well as educating the staff in key EHS topics, it also emphasised the similarities between Quality and EHS, in that both areas are involved in safeguarding our “licenses to operate”.

A significant amount of safety training (800 hours approx.) has been conducted by EHS during the year, including: EHS refresher training for all employees, EHS induction for all new employees and contractors, manual handling, risk assessments, ‘lock-out tag-out’, confined space entry, explosive risk in aerosol production and fire detection system.

A new Health & Safety Organisation was established to have safety delegates throughout the company and in the management staff. This was used to promote safety right through the company along with regular departmental safety meetings.

A new software system, IPL, was introduced for reporting of near misses, safety hazards and other safety related issues. This has resulted in a large increase, more than doubled, in the number of near misses and unsafe conditions reported, compared with previous years. There has been an emphasis on completion of risk assessments for tasks performed, with each department setting up a list of risk assessments to be completed.

Safety and Environment issues are now a topic for discussion at the weekly Gemba meeting for managers.

Finally, there has been communication every month to staff on EHS issues and there have been a number of campaigns to promote awareness of a particular Safety or Environmental topic.

Although the intense focus, the OHSAS 18001 Certification goal was not reached. Plans for 2014 will focus on improving safety behaviours through more safety training and awareness, and greater involvement of the general health and safety organisation network on site. The plan is: more safety training and awareness, have safety goals and targets included in the overall department goals, carry out more risk assessments and to improve safety management with certification to OHSAS 18001.



**Southport:**

In Southport, there were two injuries with more than one day of absence in 2013.

A number of safety initiatives were completed during the year and focused on Safety Awareness. All employees were encouraged to report all incidents, accidents and near misses and were reminded that safety is everyone's responsibility. A new safety system called Skytrust has been implemented which helps empower the employees to help identify hazards and report them correctly which will ultimately reduce workplace hazards/injuries in the future and help achieve a safe workplace. Also workplace inspections/pre-start checks and risk assessments were conducted.



## Significant environmental parameters

The most significant environmental impacts have been selected based on the following criteria.

**Substances and products**

The substances and products used in production in LEO Pharma are divided according to their origin or what characterises them.

**Energy and water**

Energy and water are included in the accounts as both are scarce resources.

**Waste**

To avoid any unnecessary waste of resources, minimisation of the waste volume is important. In addition, it is important that as much waste as possible is recycled in order to exploit all resources of the waste. Consequently, waste is considered a significant environmental parameter and is included in the accounts.

**Air pollution**

Emission of solvents, CO<sub>2</sub> and NO<sub>x</sub> to the air contributes to e.g. photochemical ozone formation, greenhouse effect and acidification. The emission of these substances is therefore considered a significant environmental parameter and is included in the accounts.

Filters have been mounted at the exhausts which emit dust. The filters are regularly maintained and replaced.

Consequently, the emission of dust to the air is insignificant and this environmental parameter is therefore not dealt with further in the accounts.

**Waste water**

The waste water contains residues of pharmaceutical products, raw materials and carriers. The content of these substances may impact on the degree of purification and efficiency of the waste water treatment works, and finally, non-retained substances may affect the marine environment. Therefore, waste water is considered a significant environmental parameter and is dealt with in the accounts.

**Noise**

High noise levels may annoy the company's neighbours. This environmental parameter is therefore significant and dealt with in the accounts.

**Contamination of ground and groundwater**

Emission of environmentally problematic substances to the ground may contaminate the ground and groundwater. This may have consequences for any extraction of groundwater in the locality. Therefore, this environmental parameter is significant and is dealt with in the accounts.

## Accounting policy

### REGISTRATION OF DATA

Data has been registered for the corporate report for 2010-2013. However, some data is missing from Southport as it has gone from being an R&D facility to manufacturing site during this period.

The registration of data has been made by key persons in the company.

The registration has been made regularly in connection with the daily operation of the company (e.g. readings), extract of data from the production control system or in connection with payment of invoices (purchase of raw materials and dispatch of waste).

Registrations have been made for internal transportation but not for external transportation.

### USE OF ENVIRONMENTAL KEY FIGURES

#### Energy

Key figures from Key2Green's website ([www.key2green.dk](http://www.key2green.dk)) have been used for the calculation of the energy consumption and the emissions of CO<sub>2</sub>, SO<sub>2</sub> and NO<sub>x</sub> from the Ballerup, Esbjerg and Southport consumption of natural gas and forklift gas. The heating value of natural gas has been based on information from DONG Energy's website.

The conversion from company energy consumption to energy consumption per average household (130m<sup>3</sup>, 3 persons) has been made on the basis of energy data from the Danish Building Research Institute, 2010 in year 2010-2012. At that time each household consumed 19.4 MWh equal to 69.84 GJ. For 2013, energy data from the Danish Building Research Institute, 2014 has been used, where each household consumes 19.0 MWh, equal to 68.4 GJ.

Conversion of energy:

1 MWh equals 3.6 GJ

1 m<sup>3</sup> of natural gas equals 0.0396 GJ

1 litre of truck gas equals 0.02486 GJ

1 m<sup>3</sup> of oil equals 0.03023 GJ

#### Water

The conversion from the company water consumption to water consumption per average household is calculated based on: one household is defined as three persons with a water consumption of 41.4 m<sup>3</sup>/year per person. (Source used for water consumption per person: the Danish Building Research Institute, 2010 in the years 2010-2012). For the year 2013, one household is defined as three persons with a water consumption of 40.1 m<sup>3</sup>/year per person (Danish Building Research Institute, 2014)

#### Waste water

For Ballerup, Esbjerg and Vernouillet, the TOC is calculated as COD divided by 3 as there are no measurements of TOC at these facilities.

#### Working hours

For the calculation of working hours, the following figures have been used:

Denmark: 18.75 business days per month x 12 months/year x 7.4 hours per day = 1,665 working hours/year

Ireland: 45 work weeks/year x 39 hours per week = 1,755 working hours/year

France: 47 work weeks/year x 35 hours per week = 1,645 working hours/year

Australia: 48 work weeks/year x 38 hours per week = 1,824 working hour/year

The total working hours are the sum of full time employees x working hours for each site. In total this was 3,424,949 working hours in 2010. In 2011, the total working hours were 3,745,271 and in 2012 the total working hours were 3,967,602. In 2013, the total working hours were 3,982,855

#### Number of days lost

This is the number of working days lost due to a work related injury. (Saturdays, Sundays and public holidays are omitted.)

## Clarification of terminology in the EHSE report

#### API

Active Pharmaceutical Ingredient

#### Average household in Denmark

130m<sup>2</sup> house and 3 persons using 19.4 MWh (69.84 GJ) in energy for heating, heating of water and electricity and 124.2 m<sup>3</sup> water according to the Danish Building Research Institute, 2010. For 2013, energy data from the Danish Building Research Institute, 2014 has been used, where each household of 3 people consumes 19.0 MWh, equal to 68.4 GJ and 120.3 m<sup>3</sup> water.

#### BOD (Biological Oxygen Demand)

BOD is an abbreviation for biochemical oxygen consumption after five days. A biological method for determining the content of biologically degradable organic substance in e.g. waste water.

#### CHP

Combined Heat and Power, integrates the production of usable heat and power (electricity), in one single, highly efficient process.

#### COD (Chemical Oxygen Demand)

COD is an expression of the amount of oxygen necessary for a chemical decomposition of the present organic substance. Thus, COD is a measuring unit for the content of the organic substance.

#### EHSE

Environment, Health, Safety and Energy

#### EPA

Environmental Protection Agency

#### Full time employees (FTE)

Recalculation of number of employees to full time employees meaning part time employees count by the number of hours they work

#### GPS

Global Product Supply, part of LEO Pharma organisation covering API Manufacturing, Finished Goods Manufacturing, Quality Control, Quality Assurance and Supply Chain Support

#### GRI

Global Reporting Initiative.

#### IPL

A Danish IT system for identification, prioritisation and solution of EHS issues.

#### LTI rate

The definition of Lost Time Injury Rate is the number of Lost Time Injuries multiplied by 1 million divided by the number of working hours worked in the reporting period. A Lost Time Injury is a work injury where the injured party has at least 1 complete day or shift off work.

#### Manufacturing sites

Sites where production takes place. The figures in the EHSE report cover all activities at the manufacturing site whether it is production, R&D, sales, finance, engineering (or something else), and other support facilities on-site.

#### MAI

An IT management system which helps companies keep track of their EHS performance.

#### R&D

Research and Development

#### TOC

Total organic carbon. The total amount of organic carbon in a water sample.



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