



LEO PHARMA A/S | GREEN ACCOUNTS

**Esbjerg 2011**



## **Green accounts 2011**

**LEO Pharma A/S**

**Esbjerg**



**This is an unauthorised translation of the Danish version**



## **Introduction**

Founded in 1908, LEO Pharma is an independent, research-based pharmaceutical company based in Ballerup near Copenhagen. LEO Pharma is wholly owned by the LEO Foundation and is one of the world's leading companies within the treatment of dermatological diseases (psoriasis, skin infections, eczema and actinic keratosis) as well as critical care (anticoagulation, nephrology and supportive treatment in cancer). LEO Pharma develops, manufactures and markets competitive, safe and efficacious drugs globally.

Today, LEO Pharma A/S is one of the top manufacturers of the anticoagulant substance heparin. Crude heparin is manufactured at the site in Esbjerg and these present green accounts cover LEO Pharma A/S' production site in Esbjerg. The accounts have been prepared for 2011.

In 2011 as in 2010, the main focus for LEO Pharma A/S' production site in Esbjerg has been the establishment of a new facility for production of crude heparin. LEO Pharma A/S has cooperated with the authorities in connection with the consideration of a new environmental approval and the new wastewater approval. These were both finally approved in the autumn of 2011.

Read more about LEO Pharma A/S and its history in the green accounts covering LEO Pharma in Ballerup or at [www.leo-pharma.com](http://www.leo-pharma.com).



## Basic information

These Green Accounts have been prepared in accordance with the requirements from the Danish Ministry of the Environment made in Executive Order no. 210 of 03/03/3010 on certain companies' obligation to submit environmental information.

<b>Company name:</b>	LEO Pharma A/S
<b>Company address:</b>	Mådevej 76, 6705 Esbjerg Ø
<b>Telephone number:</b>	44 94 58 88
<b>E-mail:</b>	leo.corporate@leo-pharma.com
<b>Website:</b>	www.leo-pharma.com
<b>Contact person:</b>	Director EHS Lykke Have
<b>CVR number:</b>	56 75 95 14
<b>P number:</b>	1.003.115.132
<b>Supervising authority:</b>	Esbjerg Kommune (the municipality of Esbjerg) is supervising authority as regards waste regulations and wastewater. Miljøstyrelsen Odense (Environmental Protection Agency Odense) is the authority as regards the company's environmental approval.
<b>Parent company:</b>	LEO Pharma A/S, Industriparken 55, 2750 Ballerup
<b>Industry:</b>	244100 – Preparation of pharmaceutical raw materials
<b>Listed as item no.:</b>	D101 "Company which manufactures organic or inorganic chemical substances, products or intermediates, including enzymes, through a chemical or biological process.
<b>Main activity:</b>	Production of crude heparin.
<b>Significant secondary activities:</b>	There are no significant secondary activities.
<b>Environmental approvals:</b>	Reassessment and environmental approval of 4 June 2002. Review of amendment of terms from Ribe Amt (The County of Ribe) on 27 July 2004. Amendment of the air emission term in connection with replacement of burner head of steam and heat boiler of 21 March 2006. Will be replaced by the environmental approval of 17 October 2011 from the Environmental Protection Agency Odense upon start-up of production in the new facilities.
<b>Sewer connection approval:</b>	The municipality of Esbjerg on 11 December 1992 The municipality of Esbjerg on 9 July 2004 (Record of decision to continue to use the above until the municipality decides otherwise). Will be replaced by the waste water approval of 23 September 2011 from Esbjerg Kommune upon start-up of production in the new facilities.
<b>Key figures for LEO Pharma A/S in Esbjerg in year 2011:</b>	
Number of employees:	11 FTE



**Qualitative description of environmental matters and use of resources:**

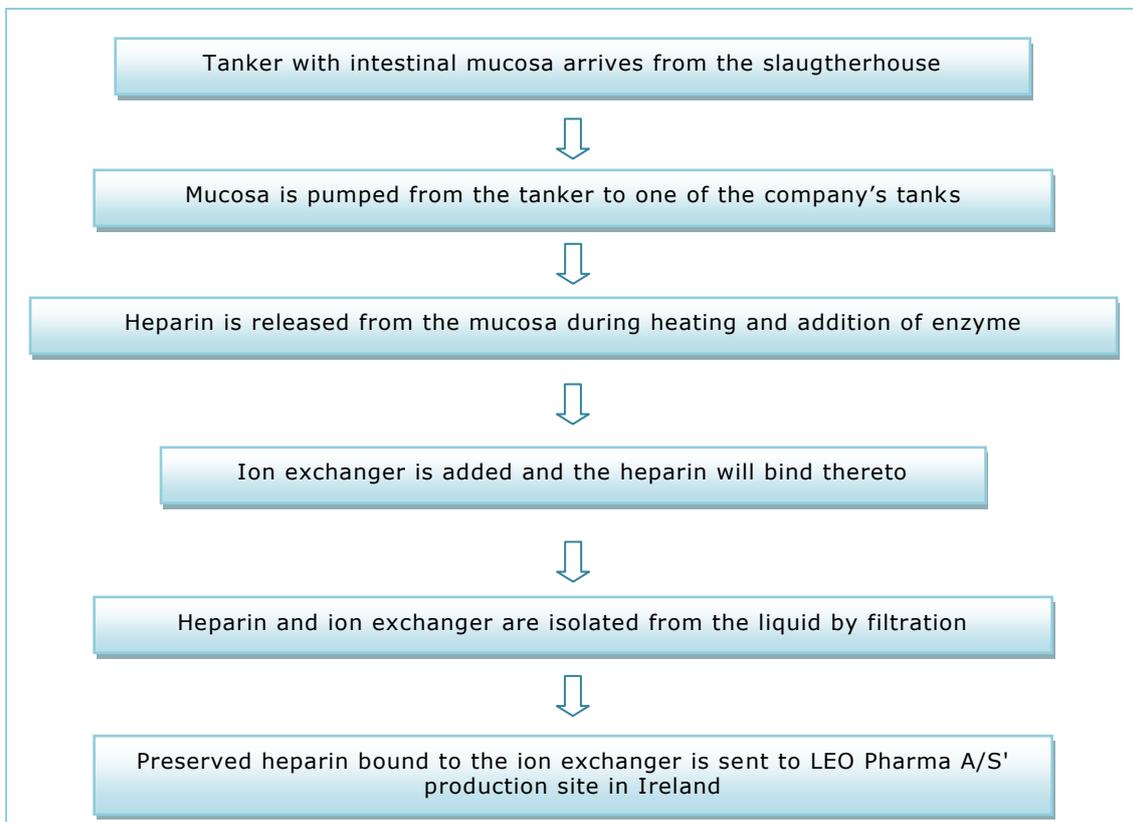
The most significant environmental matters are the raw material volume, the waste volume and the consumption of energy and water.



## Company description

The company extracts the polysaccharide heparin from slaughter waste in the form of intestinal mucosa from pigs. The concentration of heparin in mucosa is low which means that an input of approx. 74,000 tonnes mucosa results in approx. 10 tonnes of extracted crude heparin. Compared to most other industrial processes, the yield is limited and the waste volume is therefore proportionally large.

With such considerable waste volumes, recycling of waste is a must. Therefore, the waste is used as energy source in biogas plants and as manure medium at farm land. At the moment, mucosa waste is being hygiened at 70°C for at least one hour before it leaves the plant.



**Figure 1: Heparin production in outline**

As can be seen from the flow chart, crude heparin is forwarded to LEO Pharma A/S' production site in Ireland, where further purification takes place. In Ireland, two active substances are produced from the crude heparin - heparin and tinzaparin.



The active pharmaceutical ingredients are then shipped to LEO Pharma A/S in Ballerup or LEO France, where the heparin or tinzaparin bearing products are manufactured. Among these are the pharmaceutical product **innohep**<sup>®</sup>. **innohep**<sup>®</sup> is an anticoagulant and is used for prevention and treatment of blood clots.



## Management statement

This statement contains information subject to the requirements in the executive order. This includes reasons for:

- Including/not including the selected resources and environmental parameters
- Environmental policy, objectives and results
- Environmental requirements to suppliers
- Information about how employees have been involved
- Health and safety risks in cases where environmental issues and health and safety issues coincide
- Complaints
- Self-regulation
- Important changes in relation to last year's accounts (Compliance with terms)

## Reason for significance

On the basis of the company's environmental technological description, which is part of the company's environmental approval, the most significant environmental impacts have been selected based on the below criteria.

## Consumption of resources

94% of the raw materials consist of intestinal mucosa from pigs. The rest is carriers. The carriers are divided into hazard categories as this is the best way to express a potential environmental impact.

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

## Emissions

### *Waste:*

LEO Pharma A/S generates waste as a result of the company activities and as regards more than 99%, the waste comes from utilised mucosa. This activity is considered to be significant due to the large volume.

### *Emissions to the air:*

Emissions of CO<sub>2</sub>, SO<sub>x</sub> and NO<sub>x</sub> from the consumption of energy have been included in the accounts as they contribute to both greenhouse effect and acidification. Organic solvents are not used by the company and dust is not emitted. Therefore, these parameters are not included in the accounts.



The company's main raw material, intestinal mucosa, has a distinct smell. Therefore, smell is dealt with in the accounts.

*Emissions to wastewater:*

The company only has limited volumes of process wastewater. The wastewater primarily consists of sanitary wastewater and wastewater from cleaning of production and administration areas, and the composition of the wastewater is therefore fairly steady.

Key figures of wastewater are therefore used in the accounts. The key figures are calculated on the basis of previous measurements.

*Noise:*

The company is subject to the requirements in the environmental approval regarding noise. Therefore, this issue is dealt with in the accounts.

*Ground and groundwater conditions:*

Conditions regarding ground and groundwater are described in the accounts as conditions which may affect ground and groundwater are significant to the environment.

*Risk*

The company is not covered by the executive order on risk. The subject is therefore not dealt with in the accounts.

## **Environmental management**

LEO Pharma A/S' environmental management system is based on the international standard ISO 14001. The system is in the process of being implemented.

The environmental management is built around environmental projects selected based on an assessment of which positive effect the completion of the project will have on the environment. In addition, it includes the systemic requirements on preparation of instructions where it is considered necessary in order to protect the environment.

LEO Pharma A/S is a member of Miljønetværk Syd (environmental network) and has moved from being an I-company to a V-company. This means that LEO Pharma A/S has prepared an environmental statement in 2009 which meets the requirements from Miljønetværket. A new environmental statement will be sent in the spring of 2012 as it is a legal requirement to submit environmental statements every third year.



## **Environment and energy policy**

The company environment and energy policy is listed below.

***LEO Pharma is committed to the protection of the environment, the prevention of pollution and the efficient use of energy.***

***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 and energy performance.
2. Provide necessary human and financial resources to ensure that this policy is implemented and maintained.
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.

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.

## **Objectives 2011**

1. Comply with current environmental approval
2. Prepare green accounts 2010
3. Upgrade existing environmental management system
4. Prepare instructions to ensure compliance with the authority approval



### **Compliance with current environmental approval**

No violation of the terms of the approval has been observed.

The existing plant is worn down and the equipment needs replacement. Therefore, for a long period of time LEO Pharma A/S has worked to find a method for extraction of heparin from mucosa which is more optimal than the existing process. In this connection, LEO Pharma A/S has made pilot scale tests. The purpose of these tests was to investigate whether it is possible to extract heparin with the same yield level as with the existing method but with a higher tank volume than today. In addition, the purpose was to investigate whether it was possible to save energy and resources by using a higher tank volume where the entire purification and hygienisation process is made in one tank instead of three tanks as is the case today.

The tests have shown that it is possible to complete the purification process in the larger tanks but it is not possible to complete the hygienisation therein due to the fragility of the ion exchanger. Therefore, the hygienisation of the mucosa will stay in the existing plant.

In the autumn of 2011, an environmental approval for production based on the use of 70,000 tonnes mucosa per year was granted. In the end of 2011, an application has been submitted to obtain a permission to increase the production capacity to use of 120,000 tonnes mucosa per year.

From the summer of 2010, there have been increased activities on the area as a result of building and construction work. This has resulted in a higher consumption of resources than normally during the construction period (particularly electricity and water). This consumption has not been included in these accounts.

The production process will be transferred to the new facilities in the beginning of 2012.

### **The green accounts 2010**

The green accounts of LEO Pharma A/S in Esbjerg 2010 were prepared in due time and commented upon by the Environmental Protection Agency Odense. The final accounts were accepted by the Environmental Protection Agency Odense and published at [virk.dk](http://virk.dk).

In 2009, LEO Pharma A/S in Esbjerg also prepared an environmental statement to Miljønetværk Syd. Subsequently, LEO Pharma A/S in Esbjerg has received



recognition from Miljønetværk Syd in the form of flag and diploma for its environmental statement applicable for a period of 3 years.

#### **Upgrade of existing environmental management system**

The upgrade of existing environmental management system has been postponed to 2012 where this objective will be readressed.

#### **Prepare instructions to ensure compliance with the authority approval**

This task has awaited the final authority approval. In 2011, an instruction on handling of environmental accidents has been prepared. The need for additional instructions will be assessed in Q1 2012.

### **Objectives 2012**

1. To prepare green accounts for 2011 and hold meetings with relevant authorities
2. To obtain a permission to increase the production capacity to use of 120,000 tonnes mucosa per year.
3. To ensure compliance with current environmental approval and waste water approval
4. To upgrade existing environmental management system
5. To prepare instructions to ensure compliance with the authority approval of a new Heparin facility in Esbjerg

In addition to the above objectives, control measurements of noise, air and smell emissions and waste water will be made in 2012 to prove that LEO Pharma A/S complies with the set requirements/terms in the new environmental approval and in the new waste water approval

#### **Environmental requirement to suppliers**

LEO Pharma A/S makes environmental demands on suppliers as regards the requirement that there must not be any obnoxious smell in connection with the delivery of mucosa. A work instruction has been prepared for all slaughterhouses telling them how much preservatives are to be added to the mucosa.



### **Employee involvement**

The employees of the company make the registration of data for use in the green accounts. Data for use in the green accounts is reported annually to LEO Pharma A/S' central Environment, Health and Safety (EHS) department in Ballerup, who collects the reported data. The green accounts are subsequently prepared in cooperation between the relevant employees at the company and the EHS department in Ballerup.

### **Target group**

The target groups of these green accounts are the Environmental Protection Agency Odense and the municipality of Esbjerg and other parties interested in the company's environmental conditions.

### **Complaints**

LEO Pharma A/S, Esbjerg has not received any complaints in 2011.



## **Occupational health and safety**

In 2011, the company drafted a new 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.
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.

LEO Pharma in Esbjerg is already certified according to the OHSAS 18001 standard and sets annual OHS objectives. These are meant to support the long-term objectives of the LEO Pharma Group where all manufacturing sites must be certified



according to OHSAS 18001 within the end of 2015 and the lost time injury frequency must level the best in industry.

In 2011, the company had the same objectives as LEO Pharma in Ballerup:

1. Injuries – registration and investigation of 20 additional near-misses than in 2010
2. Improve the working environment in at least 20 technical areas
3. Prepare guidelines for handling of unknown substances, not relevant for Esbjerg
4. Complete at least 2 theme meetings regarding well-being at the workplace
5. Working environment for pregnant women, at least 10 health and safety groups must have reviewed their working environment and have assessed which tasks are unproblematic for pregnant women (Workplace assessment for pregnant women)
6. Prepare guidelines for health and safety for travelling employees
7. Maintain the OHSAS 18001 management system

In connection with the building of the new facility in Esbjerg, new workplace assessments must be made when the employees have worked there for a couple of months. This will not be relevant until 2012.

As regards occupational health and safety, the new facility will help diminish the following problems:

- Noise, smell and heat from the production tanks, as these will be moved to a separate tank pit
- Less manual treatments
- Improved laboratory which will no longer be a passage way for other employees

However, the new facility may have some physical limitations as it is in an existing building.



***Ad. 1 Injuries – registration and investigation of 20 additional near-misses than in 2010***

Totally for LEO Pharma A/S, 84 near-misses have been reported in 2011 against 28 in 2010. Out of these near-misses, 3 were reported from Esbjerg. Esbjerg had no injuries with absence and only one injury without absence.

***Ad. 2 Improve the working environment in at least 20 technical areas***

This objective has only been conducted in Ballerup. A list of circumstances to be checked in the technical areas has been made. As the production in Esbjerg is to move into new facilities in the beginning of 2012, it will not be relevant to look at the new technical areas until later.

***Ad. 3 Unknown substances***

The objective is not relevant for Esbjerg, as they only handle known substances.

***Ad. 4 Theme meetings on well-being on the workplace***

The theme meetings were held in Ballerup and the health and safety group from Esbjerg did not participate. However, they participated at the meeting on stress in 2010.

***Ad. 5 Working environment of pregnant women***

The working group, who has been responsible for preparation of templates for assessment of the working environment of pregnant women, has not included participants from Esbjerg. But the final templates cover most of the work functions in Esbjerg. Thus, the health and safety group in Esbjerg should be capable of conducting assessments of the working environment of pregnant women in 2012.

***Ad. 6 Preparation of guidelines for health and safety for travelling employees***

The guidelines have been prepared by a cross functional working group in Ballerup and the guidelines are available to all employees at the intranet. The guidelines are in English and include: insurance, injuries, safety, illnesses and prevention thereof, long flight trips, jetlag, legislation, driving and ergonomics. To keep this information material as brief as possible, a separate documents with further information on illnesses and prevention thereof has been prepared.



#### **Ad. 7 Maintain the OHSAS 18001 management system**

The health and safety group has completed various initiatives in connection with maintenance of the OHS management system, including safety inspections in all areas, holding of meetings in the health and safety group and update of EHS related tasks in IPL, which is LEO Pharma A/S' IT tool for identification, prioritisation and solution of OHS tasks.

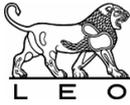
Two employees from the EHS department in Ballerup conducted an internal audit in January. They interviewed the health and safety group and some of the employees and reviewed the IPL system and took spot tests of the physical working environment. They found 2 non-conformities and 5 improvement suggestions, which were solved.

In November 2011, DS Certification conducted a follow-up audit. They were very content with the improvements of the working environment, the employees' ability to answer OHS related questions and the initiatives in the new facility. They found one minor non-conformity which was rectified before the end of the audit.

#### **The new facility**

When the production moves to the new facility during the winter of 2012, there will be a number of improvements of the working environment, including:

- Indoor driving with gas trucks will be eliminated
- Less manual treatments and internal transportation. In future, the production will have only 5 internal relocations against the present 8. Salt will be delivered with tankers and kept in a silo instead of big bags.
- Smell from the production will be diminished as the production tanks in the new facility are placed in a tank building next to the production. Thereby, the production avoids the radiant heat and the noise from the tanks.
- There is a new laboratory in the new facility which will not be a passage way as in the former laboratory. The fumehood in the new production facilities is height adjustable.



## **Overall objectives in relation to occupational health and safety at LEO Pharma A/S in 2012:**

1. Reduce the Lost Time Injury\* frequency to a maximum of 5 corresponding to 11 occupational injuries at 1374 full time employees.

$$\text{LTI} = \frac{(\text{number of injuries with more than one day of absence from work} * 1,000,000 \text{ working hours})}{\text{Total working hours}}$$

In 2010, LEO Denmark reached an LTI of 7. The LTI frequency includes the number of injuries with absence beyond the day of the injury. One of the methods to reduce the number of injuries is to focus on near-misses. LEO Esbjerg had an LTI frequency of 0 in both 2010 and 2011 since there has been no injuries with absence beyond the day of the injury.

2. Complete chemical workplace assessments in at least eight departments.
3. Increase the knowledge level of the health and safety groups on psychological working environment by offering both health and safety and management representatives four supplementary courses of 1½-2 days' length in 2012.
4. Working environment for pregnant women. At least 10 health and safety groups must have their working environment reviewed in 2012 and assessments must be made as to which tasks are unproblematic for pregnant women.
5. Improve the working environment in at least 50 technical areas (technical rooms) in 2012.
6. Employee focus on occupational health and safety. Four news letters will be published and two competitions/campaigns on occupational health and safety will be held in 2012.
7. Develop and maintain the OHSAS 18001 management system. All departments must allocate sufficient resources for the health and safety and management representatives to perform their tasks.



### Self-regulation

Operational controls of boiler systems have been conducted once every half year. Temperature control of the mucosa is made in connection with production, hygienisation and removal.

Incoming raw materials and carriers, dispatched crude heparin to Ireland and the volume of dispatched mucosa wastewater are registered.

There is no self-regulation terms attached to the environmental approval from 2002 as subsequently amended.

In the environmental approval from 2008 regarding permission to set up a pilot tank, terms have been set regarding noise measurement as documentation for compliance with the noise requirement.

In the autumn 2009, noise measurements/calculations have been made of the noise load which LEO Pharma A/S, Esbjerg puts on its surroundings when manufacturing in the present building.

In the environmental approval applicable for manufacturing in the present building, noise thresholds have been set for areas of industry, land-zone without housing, land-zone with housing and area of parks and graveyards.

The results of the investigation of the noise load show that the noise terms are met. Similar calculations on Sundays prove that the noise terms are met in all five areas. When the noise terms are met on Sundays, they will also be met on Saturdays, where the requirements are relaxed compared to Sundays, as the company's operational conditions are the same on both Saturdays and Sundays.

### Non-conformities compared to the previous accounts

To provide an overview of the environmental performance of the site, this is demonstrated in the below table as produced unit in the years 2007 - 2011.

	2007	2008	2009	2010	2011
Consumption of raw materials/product (kg/kg)	8,039	8,013	8,021	8,025	8,009
Energy consumption/product (kWh/kg)	877	856	868	876	832
Water consumption/products (litre/kg)	1,885	1,841	2,031	2,002	2,220
Acid gasses/product (kg/kg)	0.1*	0.1*	0.1*	0.1*	0.1*
Greenhouse gasses/product (kg/kg)	160*	158*	159*	163*	155*
Waste volume/product (kg/kg)	8,315	8,438	8,225	8,380	8,492
Wastewater volume/product (litre/kg)	603	589	650	641	710

\*Note: The load of the energy consumption has not been included. See also under the section on energy.

**Table 1: Environmental performance per produced unit**



The table shows that the yield (consumption of raw material/product) in 2011 almost corresponds to the yield in 2010.

There is drop of 5% in the consumption of carriers per produced kg product while the consumption of mucosa per produced kg product is stable. The total production of crude heparin has increased in 2011 compared to 2010, because the site has received an increased mucosa volume.

Compared to 2010, the relative energy consumption has decreased by 5%. The consumption of energy has not increased with the same speed as the produced volume. The reason should be found in a reduced energy consumption for heating in the binding period of the process. The drop in energy consumption exists despite increased energy consumption for heating of raw materials in the initiation of the process as more raw materials are imported and as these raw materials have a low temperature upon receipt. Furthermore, 2011 had 12% fewer degree days than in a normal year and 24% fewer degree days than in 2010. A decreased number of degree days results in a lower energy consumption for heating purposes. The energy consumption for construction activities is not included in these green accounts.

The table demonstrates that the relative water consumption increases in 2011 compared to 2010. The increase in the relative water consumption in 2011 is a result of increased cleaning of the tank containers as increasingly higher volumes of mucosa have been delivered in small tank containers within the past years.

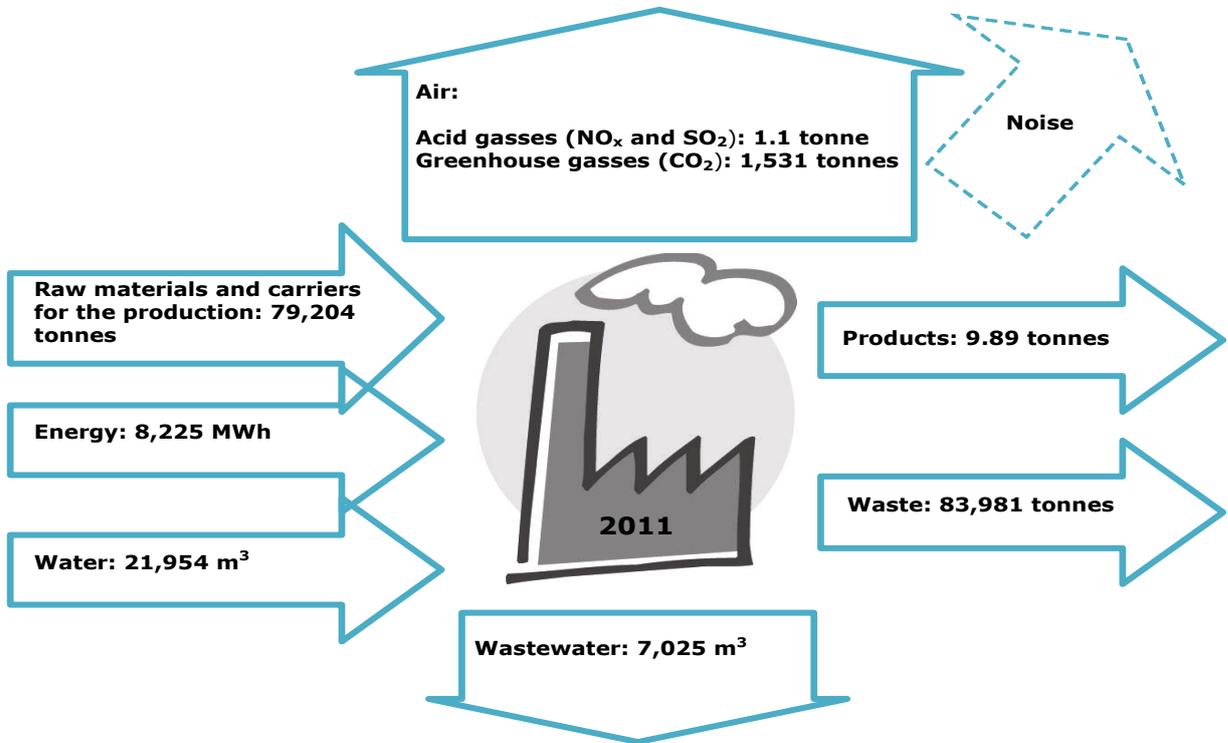
The wastewater volume has increased from 2010 to 2011. This is because the waste water volume is estimated as a fixed percentage of the water consumption.

***Compliance with terms in the environmental approval***

The company complies with current terms in the environmental approval as subsequently amended.



## Account of the environmental performance



**Figure 2: Environmental performance 2011 in outline**

For the purpose of a more detailed perspective of the environmental performance, the following items will be reviewed:

- Input (raw material, energy, water)
- Output (products, waste, emissions (wastewater, solvents to air, dust, noise, smell))
- Ground and groundwater issues
- Risk (accidents and underground tanks)
- Compliance with the environmental approval



## Input

### Raw materials

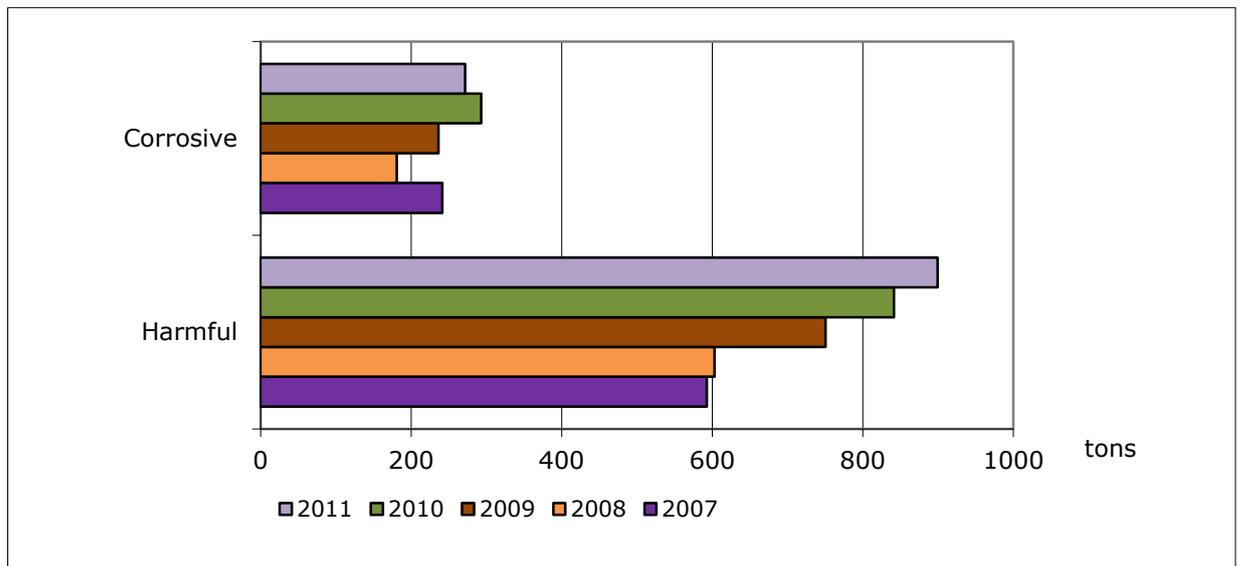
The company uses the following categories of raw material:

Consumption of raw materials, stated in tonnes	2007	2008	2009	2010	2011
Agricultural products	44,750	48,034	52,837	60,771	74,171
Organic compounds (enzymes)	20	21	22	26	32
Inorganic acids, bases and salts	3,197	3,270	3,647	4,227	5,000
Detergents	~0	~0	0.2	0.2	0.9
<b>Total</b>	<b>47,966</b>	<b>51,324</b>	<b>56,507</b>	<b>65,024</b>	<b>79,204</b>

**Table 2: Raw material categories**

The most important raw material is agricultural products (intestinal mucosa). Mucosa is a waste product from slaughterhouses and contains the important polysaccharide heparin, which is extracted at the company. Mucosa represents approx. 94% of the total raw material consumption. In the above statement of agricultural products, the added preservative solution has been included.

The remaining 6% consists of other organic compounds (enzymes), inorganic salts, hydrochloric acid and sodium hydroxide.



**Figure 3: Consumption of substances with hazard symbol.**

As can be seen from the above figure, the consumption of corrosive substances has increased and decreased over the years. The variation in consumption depends of the waste volume which is allocated for bio-gasification. The corrosive substance



iron chloride is added to the waste allocated for bio-gasification to bind sulphur in the waste. In 2011, a smaller volume of waste for bio-gasification than in 2010 has been submitted, resulting in a smaller consumption of iron chloride. In the past three years on the other hand, there has been an increased consumption of corrosive substances in the production process as a result of the increased raw material volume.

The consumption of harmful substances depends on the mucosa volume processed. Consequently, the increased mucosa volume has resulted in an increased consumption of harmful substances as the preservative used is classified as harmful.

The company does not use any undesired substances in the production.

### Energy

The consumption of energy in 2011 corresponded to the consumption of light, heat, cooking etc. of 366 average domestic households.

The table below demonstrates how the distribution has been within the different types of energy within the past five years.

Energy consumption in MWh	2007	2008	2009	2010	2011
Natural gas	4,620	4,881	5,427	6,437	7,472
Electricity	596	581	667	640*	732
Forklift gas	17	21	21	21	21
<b>Total</b>	<b>5,233</b>	<b>5,483</b>	<b>6,115</b>	<b>7,210</b>	<b>8,225</b>

\*The consumption of electricity has been corrected as to not include electricity from construction work

**Table 3: Consumption within the different types of energy**

As can be seen from the table, there is an increase in the consumption from 2010 to 2011, which is a result of an increased volume of produced crude heparin and an increased need for heating of the received raw materials.

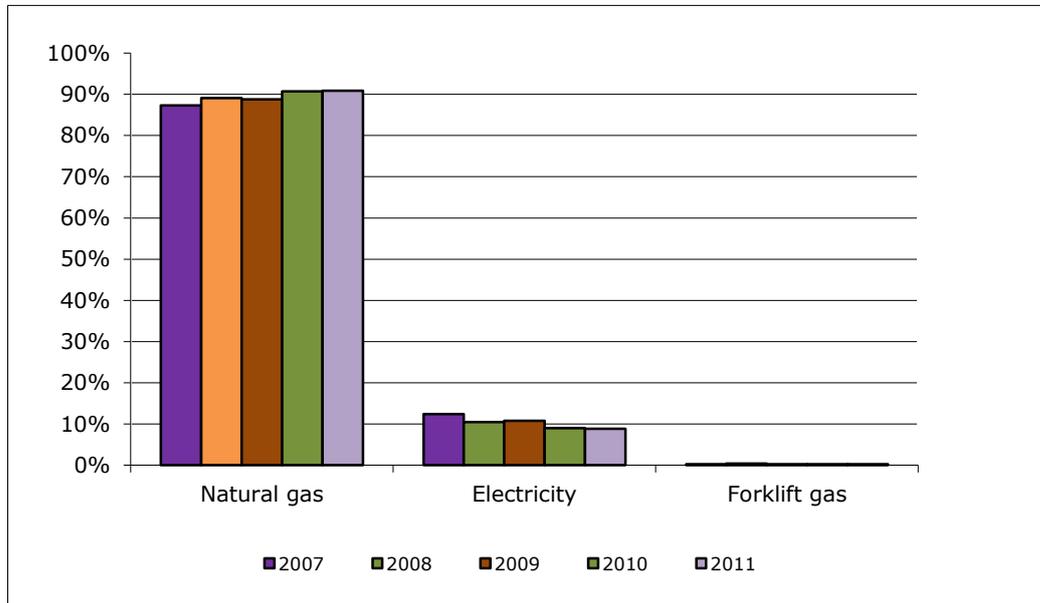
If the energy consumption is compared, it reflects a stabile operation. The table below displays the energy consumption compared to the total energy consumption at the site within the past five years.

	Unit	2007	2008	2009	2010	2011
<b>Energy consumption</b>	<b>MWh</b>	5,233	5,483	6,115	7,098	8,225
<b>Mucosa</b>	<b>tonne</b>	44,750	48,034	52,837	60,711	74,171
<b>Energy consumption/tonne mucosa</b>	<b>MWh/t</b>	0.12	0.11	0.12	0.12	0.11

**Table 4: Energy consumption compared to the total energy consumption within the past five years**



Figure 4 displays the energy consumption of different types of energy.



**Figure 4: Distribution of energy on types of energy**

### Water

The water consumption in 2011 corresponded to approx. 177 households (domestic).

The table below shows the development in the water consumption within the past five years.

	2007	2008	2009	2010	2011
<b>Water consumption in m<sup>3</sup></b>	11,247	11,793	14,307	16,220	21,9540

**Table 5: Development in the water consumption**

Water is used for production processes, sanitary purposes and cleaning.

As can be seen, there is an increase in the water consumption in 2011 compared to 2010. The increase is a result of boosted production owing to an expanded mucosa volume for extraction of heparin and thereby increased water consumption for the production of steam which is added in the process. The relative water consumption is augmented within the past three years as a result of increased cleaning of tank containers (more small containers). In 2011, the increased water consumption is also a result of conditioning of new resin and an increased water consumption for



improvement of the water treatment of water used for steam production (see table 6).

	Unit	2007	2008	2009	2010	2011
<b>Water consumption</b>	<b>m<sup>3</sup></b>	11,247	11,793	14,307	16,220	21,954
<b>Mucosa</b>	<b>tonne</b>	44,750	48,034	52,837	60,771	74,171
<b>Water consumption/tonne mucosa</b>	<b>m<sup>3</sup>/t</b>	0.25	0.25	0.27	0.27	0.30

**Table 6: Relative water consumption**

## Output

### Product

The table below shows the company's produced volumes of crude heparin:

Produced volumes in tonnes	2007	2008	2009	2010	2011
<b>Crude heparin</b>	5.97	6.41	7.05	8.10	9.89

**Table 7: Produced volumes of crude heparin**

The produced volume has increased during 2007-2011. As can be seen from the table below, the relative yield is constant.

Relative yield	Unit	2007	2008	2009	2010	2011
<b>Crude heparin</b>	<b>tonne</b>	5.97	6.41	7.05	8.10	9.89
<b>Mucosa</b>	<b>tonne</b>	44,750	48,034	52,837	60,771	74,171
<b>Relative yield</b>	<b>10<sup>-3</sup></b>	0.13	0.13	0.13	0.13	0.13

**Table 8: Relative yield**

The crude heparin is shipped in intermediate bulk containers to LEO Pharma's site in Ireland for further purification.

### Waste

The waste of the company is categorised within the following kinds of treatment:

Types of waste in tonnes	2007	2008	2009	2010	2011
Recycling	49,585	54,015.7	57,919.6	67,868	83,953
Incineration	20	22.7	26.0	31.8	19.9
Special treatment	0	0	0	0.7	0
Waste deposit*	10	7.9	1.4	4.7	8.5
<b>Total</b>	<b>49,615</b>	<b>54,046.3</b>	<b>57,947.0</b>	<b>67,904.9</b>	<b>83,981.3</b>

\* From 2009 delivered as waste for sorting.

**Table 9: Kinds of treatment**



The major part of the waste (> 99%) consists of intestinal mucosa, from which the heparin is extracted. This waste is utilised either in bio-gasification producing heat or as manure medium at farm land. Therefore, the high recycling percentage. In addition to mucosa, paper and cardboard waste is recycled (0.83 tonnes in 2011) as well as iron and metal (4.04 tonnes in 2011).

The fraction, special treatment is the waste volume which is sent to Kommunekemi a/s. No hazardous waste was generated in 2005-2009. In 2010, 0.7 tonne hazardous waste was generated. This is hazardous waste from tidying-up of chemicals as a part of a 5S activity in connection with the implementation of LEAN. In 2011, no hazardous waste has been delivered to kommunekemi a/s.

Waste suited for incineration is sent for incineration. The volume is considerably lower in 2011 compared to 2010. In 2010, a thorough tidying was made which resulted in an extraordinarily high waste volume. The waste consists of empty packaging from various raw materials, household waste, straw etc.

Waste (such as e.g. construction waste), which is sent for sorting, is not suitable for incineration. The increased volume is due to the fact that the craftsmen have used the site containers instead of their own containers at the construction site.

## **Emissions**

### *Wastewater*

The wastewater contains sanitary wastewater and wastewater generated in connection with cleaning.

In 1997, the municipality of Esbjerg has a number of analyses taken of the wastewater. These showed that the requirements in the sewer connection approval were met. Wastewater analyses have not been taken since then. In 2012, 4 24-hour tests will be taken spread evenly over the year.

As the company practice within the wastewater area has not changed considerably since 1997, it is assessed that the concentration of substances in the wastewater in 1997 reflects the content in the other years.



<b>Substance/ Parameter</b>	<b>Total discharged volume*</b>					<b>Potential environmental impact</b>
	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	
Process wastewater (m <sup>3</sup> )	3,599	3,774	4,578	5,190	7,025	
COD (tonne)	2.4	2.5	3.1	3.5	4,7	Deoxygenation
Suspended substance (tonne)	0.4	0.4	0.5	0.6	0,8	Clogging of sewer
Total nitrogen (tonne)	0.2	0.3	0.3	0.4	0.5	Eutrophication causing deoxygenation
Total phosphorus (tonne)	~0 28 kg	~0 29 kg	~0 36 kg	~0 40 kg	~0 55 kg	Eutrophication causing deoxygenation
Grease (tonne)	0.1	0.1	0.2	0.2	0.3	Clogging of sewer

\* Data calculated on the basis of analysis results from 1997.

**Table 10: Substances measured in the wastewater and related environmental impacts.**

The wastewater is led to purification at Rensningsanlæg Øst, Mådevej, Esbjerg, (wastewater treatment works) in order to minimise the risk that the above potential environmental impacts arise.

The wastewater volume was higher in 2011 compared to 2010. The reason is increased production and increased water consumption for cleaning of several small tank containers and conditioning of resin. Water from the new wastewater treatment works has also contributed to an increased waste water volume.

#### *Emissions to air*

The activities of the company cause a number of acid gasses and greenhouse gasses to be emitted into the air as a result of the energy consumption. In the statement, the emission of CO<sub>2</sub>, SO<sub>2</sub> and NO<sub>x</sub> stemming from the electricity production has not been included. This emission is calculated where the electricity is generated in order to avoid double reporting to the EU. The emissions are displayed in table 11. In the text below table 11, a statement of the CO<sub>2</sub> emission from the electricity consumption is made.



Substance						Potential environmental impact
	2007	2008	2009	2010	2011	
Carbon dioxide CO <sub>2</sub>	955	1,010	1,122	1,319	1,531	Greenhouse effect
Sulphur dioxide SO <sub>2</sub>	0	0	0	0	0	Acidification
Nitrogen oxides NO <sub>x</sub>	0.7	0.7	0.8	1.0	1.1	Acidification

**Table 11: Energy consumption converted to emission of CO<sub>2</sub>, SO<sub>2</sub> and NO<sub>x</sub> stated in tonnes and the potential environmental impact related thereto.**

If electricity has been included in the above, the CO<sub>2</sub> emission would have been 1,859 tonnes in 2011. Key2Greens current key figures of the years in question are used for the statement.

In 2007, the part of the CO<sub>2</sub> figure stemming from electricity production amounted to 274 tonnes.

In 2008, the part of the CO<sub>2</sub> figure stemming from electricity production amounted to 272 tonnes.

In 2009, the part of the CO<sub>2</sub> figure stemming from electricity production amounted to 316 tonnes.

In 2010, the part of the CO<sub>2</sub> figure stemming from electricity production amounted to 296 tonnes.

In 2011, the part of the CO<sub>2</sub> figure stemming from electricity production amounted to 328 tonnes.

The total volume of flue gasses emitted by the company in 2011, amounted to a total calculated volume of 9,170,253 m<sup>3</sup> flue gas.

#### *Solvents to the air*

No solvents are used by LEO Pharma A/S, Esbjerg.

#### *Dust*

Dusty processes are not part of the production.

#### *Noise and vibrations*

Noise and vibrations from the area mainly originate from lorry transports to and from the site.



In the autumn of 2009, noise measurements/calculations have been made of the noise load which LEO Pharma A/S, Esbjerg puts on its surroundings when manufacturing in the existing building.

In the environmental approval, noise thresholds have been set for areas of industry, land-zone without housing, land-zone with housing and area of parks and graveyards.

The results of the investigation of the noise load showed that the noise terms are met in the area of industry and in land-zone with and without housing. In the area designated for parks and graveyards, there is a slight violation of the noise threshold at night. In connection with the preparation of the environmental approval for the expansion of the production, it has turned out that the reference point for the area designated for parks and graveyards has not been placed correctly. The correct spot at the boundary for the park and graveyard area is approx. 200 m. further to the north and thereby 200 m further away from the company's property line. New calculations from this spot show that the noise threshold is met at the new reference point after the future expansion of the site. The assessment of the compliance with the term has been based on normal practice of the Environmental Protection Agency.

List of the results from autumn 2009 (with the previously used reference point for the area of parks and graveyards) is represented below:

Noise load Stated in dB(A)	Working days					
	6 a.m. 6 p.m.		6 p.m – 10 p.m		10 p.m. – 6 a.m.	
	L <sub>r</sub>	Noise th.	L <sub>r</sub>	Noise th.	L <sub>r</sub>	Noise th.
Industrial area Mådevej 67	57+/- 4	60	53 +/- 5	60	53 +/- 5	60
Industrial area Mådevej 80	57+/- 3	60	39 +/- 3	60	60 +/- 4	60
Industrial area Mådevej 72	60 +/- 4	60	55 +/- 5	60	55 +/- 5	60
Land-zone with housing Mådevej 89	30+/- 3	55	17 +/- 3	45	31 +/- 3	40
Area of parks and graveyards Måde Kirkevej 9	36 +/- 3	45	26 +/- 3	40	38 +/- 3	35

(L<sub>r</sub>: Noise load) (Noise th.: Noise threshold in the environmental approval) (+/- : Uncertainty of measurement)



In the end of 2011, a noise measurement was made which demonstrates that the noise terms in the environmental approval from October 2011 can be met in a production based on 120,000 tonnes mucosa per year.

#### *Smell*

Mucosa has a distinct smell. Therefore, local exhaust ventilation has been mounted on all reaction tanks. The exhausts have been led to the roof. No complaints have been received regarding smell from the company's operation in Esbjerg in 2010.

#### **Ground and groundwater**

Ground and groundwater are not considered to be endangered by the activities at the area. This is primarily due to the fact that no solvents or other substances are used which may lead to contamination of the groundwater if spilled or discharged to the ground.

Spills or discharge in connection with an accident are only considered to cause minor, local ground contamination which will be possible to isolate, excavate and remove in accordance with current environmental legislation.

In February, Region Syddanmark (the region of Southern Denmark) has mapped a small part of the lot as knowledge level 1. The area includes a previous tank pit for over ground oil tanks. The mapping as knowledge level 1 means that the ground may be contaminated. The mapping has been based on the fact that there have been activities which may have contaminated the ground.

Prior to the initiation of the present construction work, the area which has been excavated for new buildings has been analysed for ground contamination. 8 borings have been made in the area and no signs of ground contamination in the area were found.

#### **Risk**

The company is not subject to the executive order on risks (Executive order no. 1666 of 14 December 2006 from the Ministry of the Environment and the amending executive order no. 1694 of 22 December 2010 on control with the risk of large accidents with hazardous substances) and is therefore not considered as a risk company.

#### *Accidents*

No accidents have been registered at LEO Pharma A/S, Esbjerg in 2011.

#### *Underground tanks*

Underground tanks are not present at the company's area.



## **Accounting policy**

### **Registration of data**

Data has been registered for 2007-2011.

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) or in connection with payment of invoices (e.g. 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 company's consumption of electricity, natural gas and forklift gas. The heating value of natural gas has been based on information from DONG's website.

The conversion from company energy consumption to energy consumption per average household (130 m<sup>2</sup>, 3 persons) has been made on the basis of energy data from the Danish Building Research Institute.

#### **Flue gas**

For the determination of the flue gas volume, the following key figures have been used (data: Weishaupt): 1 m<sup>3</sup> gas emits 13.5 m<sup>3</sup> flue gas.

#### **Water**

As regards conversion from the company water consumption to water consumption per average household, one household is defined as three persons with a water consumption of 41.3 m<sup>3</sup>/year per person. Source used for water consumption per person: the Danish Building Research Institute.



## Clarification of terminology in the green accounts

### *Audit*

Internal or external inspection/control of whether the company or parts of the company meet the current requirements within environment, quality and/or occupational health and safety.

### *Acidification*

The reduction of the pH value in the environment. The reason is emission of certain gasses which form acid when mixed with water resulting in acid rain.

### *Binding period*

The period where the heparin binds to the resin.

### *Bio-gasification*

Conversion of organic substance and bacteria into the gas methane (CH<sub>4</sub>). The methane gas is collected and sent for incineration at a combined heat and power plant whereby district heating and electricity is generated.

### *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 of the content of the organic substance.

### *Emission*

Emission to air, water and ground.

### *Environmental management*

Environmental management implies that the company works systematically and focused with its environmental performance. Environmental management results in environmental benefits and benefits relating to resources.

### *Eutrophication*

An increase of algae and other organisms in the water environment.

### *FTE*

Full Time Employees

### *Greenhouse effect*

Global warming. The reason is an increased concentration of gasses omitting the heat from leaving the ground.

### *I-company*

"I" for "interest": companies, educational institutions etc. which would like to keep abreast of the work and activities of Miljønetværk Syd.

### *ISO 14001*

In the environmental management standard "ISO 14001", the **I**nternational **O**rganisation of **S**tandardisation has established a number of requirements to companies' environmental management. If the company complies with these requirements, the company is able to obtain a certificate if it complies therewith.



*Mucosa*

Intestinal mucosa from pigs.

*OHSAS 18001*

The international standard for occupational health and safety management systems OHSAS 18001 (Occupational Health and Safety Series) determines a number of requirements to companies' OHS management and the companies are able to obtain a certificate if they comply therewith.

*Polysaccharide*

Any class of carbohydrates, such as starch, cellulose and glycogen, consisting of a number of monosaccharides joined by glycosidic bonds.

*5S*

A LEAN tool. The 5 S's are: sort, store, shine, standardise, sustain.

*Substances subject to labelling*

Manufacturers and importers are under an obligation to classify chemical substances/products in accordance with the Danish executive order on classification. A classification is to determine which hazardous properties a substance/product holds. Substances/products must be labelled if they hold hazardous properties.

*Suspended substance*

Insoluble matter in the wastewater which sinks to the bottom. By sedimentation or filtration, it can be removed from the wastewater.

*V-company*

"V" for "virksomhed" (company): V-members are bound to prepare an environmental statement within 3 years after registration, cf. the requirements from Miljønetværk Syd.

*Work place assessments (WPA)*

An assessment of the health and safety conditions in the company.

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