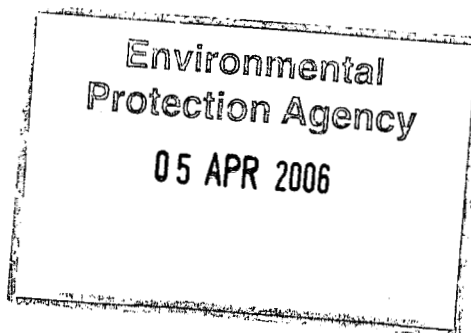


**Fingal County Council Comhairle Contae Fhine Gall**



Ms. Noeleen Roche  
Licensing Unit  
Office of Licensing and Guidance  
Environmental Protection Agency  
Headquarters, PO Box 3000,  
Johnstown Castle Estate  
County Wexford  
Ireland



4<sup>th</sup> April 2006

**Regarding: Helsinn Chemicals Ireland Limited – Reg No. 776**

Dear Noeleen,

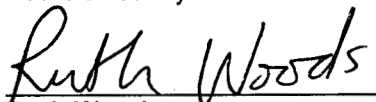
Further to your correspondence of the 9<sup>th</sup> February 2005, Fingal County Council have reviewed reports submitted by Helsinn Chemicals Ireland Limited and information subsequently received from the EPA in relation to the IPPC License Review.

It is confirmed that that an Order under Section 22 of the Local Government (Water Pollution) (Amendment) Act, 1990.

I enclose the Sanitary Authority Response report and the report produced by Imelda Averill the Senior Executive Scientific Officer Dublin City Council Central Laboratory. These detail Fingal County Council requirements with respect to discharges to the foul sewer.

If you have any queries, I can be contacted at 01 8906776 or alternatively at [ruth.woods@fingalcoco.ie](mailto:ruth.woods@fingalcoco.ie)

Yours sincerely

  
Ruth Woods  
A/Senior Executive Engineer  
Water Services Department

Water Services Department  
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EPA  
Main File ☒  
Public File ☒  
Evaluation File ☒  
Date 5.4.06 (AMG)

Water is precious. Let's conserve it.  
Tá uisce luachmhar. Caomhnáimís é.



## **SANITARY AUTHORITY RESPONSE**

*Name of Sanitary Authority : Fingal County Council*

*Address : P.O. Box 174  
Fingal County Hall  
Swords  
County Dublin*

*Name of Facility : Helsinn Chemicals Ireland Ltd.  
Damastown,  
Mulhuddart.  
Dublin.15.*

*IPPC Register Number: 776*

<b>Consent granted subject to the consent conditions outlined below</b>	<b>Yes</b>
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### **CENTRAL LABORATORY CONSENT CONDITIONS**

<b>GENERAL CONSENT CONDITIONS WW-D1</b>	<b>Condition to be included (Yes/No)</b>
1. No specified emission to sewer shall exceed the emission limit value or load set out in Schedule B : <i>Emission Limits to Sewer</i> . There shall be no other emission to sewer of environmental significance.	Yes
2. The Licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out in <i>Schedule C</i> .	Yes
3. Monitoring and analyses equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission or discharge.	Yes
4. The licensee shall permit authorised persons of the Agency and the Sanitary Authority to inspect, examine and test, at all reasonable times, any works and apparatus installed in connection with the trade effluent and to take samples of the process effluent.	Yes
5. All automatic monitors and samplers shall be functioning at all times (except during maintenance and calibration) when the activities are being carried out unless alternative sampling or monitoring has been agreed in writing by the Agency for a limited period. In the event of the malfunction of any continuous monitor, the licensee shall contact the Agency as soon as practicable, and alternate sampling and monitoring facilities shall be put in place. Prior written agreement for the use of alternative equipment, other than in emergency situations, shall be obtained from the Agency.	Yes
6. The licensee shall record all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence.	Yes
7. The licensee shall provide safe and permanent access to all on-site sampling and monitoring points and off-site points as required by the Agency.	Yes
8. No substance shall be present in such concentrations as would constitute a danger to sewer maintenance personnel working in the sewerage system or would be injurious to the construction of the sewer or would interfere with the operations of a downstream wastewater treatment works.	Yes

9. No substance shall be discharged in a manner, or at a concentration which after initial dilution in the receiving waters to which the Sanitary Authority sewage is discharged , causes tainting of fish or shellfish.	Yes
10. No emission to sewer shall take place which gives rise to any reaction within the sewer or to the liberation of by-products which may be of environmental significance.	Yes
11. The licensee shall ensure that the effluent shall not contain petroleum hydrocarbons or organic solvents (including chlorinated organic solvents) which would give rise to flammable or explosive vapours in the sewer.	Yes
12. A summary report of the results of analysis of effluent discharged to the sewer <u>with relevant volumes discharged</u> shall be forwarded to the sanitary authority on a quarterly basis.	Yes
13. Non-trade effluent wastewater ( e.g. firewater, accidental spillages ) which occurs on site shall not be discharged to the sewer without the prior authorisation of Fingal County Council.	Yes
14. The licensee shall at no time discharge or permit to be discharged into the sewer any liquid matter or thing which is or may be liable to set or congeal at average sewer temperature or is capable of giving off any inflammable or explosive gas or any acid, alkali or other substance in sufficient concentration to cause corrosion to sewer pipes, penstock and sewer fittings or the general integrity of the sewer.	Yes

#### ADDITIONAL GENERAL CONSENT CONDITIONS

15. A log detailing the usage of all cooling water and boiler water treatment chemicals shall be kept by the Licensee and submitted to Fingal County Council on an annual basis.
16. Best available technology ( BAT ) for the relevant sector ( Manufacture of Fine Chemicals ) shall be used to prevent, minimise, manage and treat pollutants in the wastewater stream discharging to foul sewer under this consent.
17. The Licensee shall maintain, or have maintained the on-site effluent treatment systems.
18. The Licensee shall provide Fingal County Council with flow data for any effluent batch discharged to sewer that is sampled under Fingal County Council's monitoring and charging programmes.
19. The Licensee shall provide Fingal County Council with COD concentration data for any effluent batches discharged to sewer as required under Fingal County Council's monitoring and charging programmes.

## Limit Values for Trade Effluent to Sewer

### Schedule B - Emissions to Sewer

Emission point reference no: **WW-D1**

Emission to (sewer description): **Macetown Sewer**

Grid Reference : **304866E, 241164N**

Volume to be emitted: Maximum in any one day : **50.0 m<sup>3</sup>**  
 \_\_\_\_\_ Maximum rate per hour : \_\_\_\_\_ m<sup>3</sup>

Parameter	Emission	Limit Value		Parameter to be limited (Yes/No)
	<b>Grab</b>	<b>Daily Mean</b>	<b>Daily Mean</b>	
	<b>Sample (mg/l)</b>	<b>Concentration (mg/l)</b>	<b>Loading (kg/day)</b>	
BOD	N/A	N/A	100.0	Yes
COD	N/A	N/A	400.0	Yes
Suspended Solids	500	400	20.0	Yes
Sulphates (as SO <sub>4</sub> )	500	500	25.0	Yes
Fats, Oils, Grease	100	100	5.0	Yes
pH	6 - 10	6 - 10	-	Yes
Temperature	42 degrees C	42 degrees C		Yes

### ADDITIONAL PARAMETERS

Phosphates ( as PO <sub>4</sub> -P )	50	50	2.5	Yes
Total Nitrogen ( mg/l N )	1000	1000	50.0	Yes
Total Phosphorus (mg/l P)	100	100	5.0	Yes

## Frequency of Monitoring Trade Effluent to Sewer

### Schedule C - Monitoring of Emissions to Sewer

Emission point reference no: WW-D1

Parameter	Monitoring Frequency	Sampling Method/Type (grab, continuous)
Flow to sewer	Continuous during batch discharges	Continuous
BOD	Monthly	Grab sample
COD	Each Batch	Grab sample
Suspended Solids	Monthly	Grab sample
Sulphates (as SO <sub>4</sub> )	Monthly	Grab sample
Fats, Oils, Grease	Monthly	Grab sample
pH	Continuous	Continuous
Temperature	Continuous	Continuous

### ADDITIONAL PARAMETERS

(if required)

Phosphates ( as PO <sub>4</sub> -P )	Monthly	Grab Sample
Chloride	Monthly	Grab Sample
Total Nitrogen	Monthly	Grab Sample
Total Phosphorus	Monthly	Grab Sample
Organic Compounds*	Quarterly	Grab Sample
Toxicity ( Freshwater Aquatic )	Quarterly	Grab Sample
Toxicity ( ISO 8196 )	Quarterly	Grab Sample
Activated Sludge		

\* Screening for Priority Pollutant List Substances. This analysis shall include those organic solvents in use in the processes, which are likely through normal process operations, to be discharged to the wastewater stream being discharged to sewer.

Central Laboratory, Engineering Department,  
68/70 Marrowbone Lane, Dublin 8

Saotharlann Lárnach, Roinn Innealtóireachta,  
68/70 Lána Mhuire Mhaith, Baile Átha Cliath 8  
T. 01 222 4341 F. 01 454 4797 E. imelda.averill@dublincity.ie

Ms. Noeleen Roche  
Licensing Unit  
Office of Licensing and Guidance  
Environmental Protection Agency  
Headquarters, PO Box 3000,  
Johnstown Castle Estate  
County Wexford  
Ireland

4<sup>th</sup> April 2006

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Report provided by Ms. Imelda Averill, Senior Executive Scientific Officer, Dublin City Council

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Re : Application from the EPA for Consent to Discharge Trade Effluent to Sewer.  
**IPPC No.776 - Helsinn Chemicals Ireland Ltd., Damastown, Mulhuddart, D.15.**  
**( previously IPC No. 125 )**

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Under the IPPC Directive of 1996, the Protection of the Environment Act, 2003, and the relevant licensing regulations, existing IPC licences are currently being reviewed by the EPA and new IPPC licenses are being issued.

Helsinn Chemicals Ireland Ltd. has applied to the EPA ( and to Fingal County Council ) to review the consent originally issued as part of IPC No.125 in 1997, as part of their new application for IPPC No.776. A site meeting held on 03/03/06 was attended by Ms.Ruth Woods and Mr.Jim Kavanagh ( FCC ), Ms.Imelda Averill ( Central Laboratory ), Dr.David Keenan and Ms.Lisa Cassidy ( Helsinn Chemicals ) and Mr.Tadg O'Flaherty ( Arup Consultant to Helsinn Chemicals ).

### History and Review Rationale

Helsinn Chemicals Ireland's ( HCI ) original consent was tailored to the manufacture of a single anti-inflammatory pharmaceutical product ( Nimesulide ) in 1996. They have commenced the manufacture of Isoprinosin and Oxaprozin in the intervening years. HCI wishes to further diversify its range of products by at least three or four between 2006 and 2012.

They have requested a mass emission ( load ) based consent, for certain parameters, rather than a combined concentration and mass emission based consent, as is normally issued by Fingal County Council. Their site in Mulhuddart has additional space that the company intends to develop over the 2006 to 2012 period. An investment of some 2 million euro on equipment is currently under way to expand the plant's manufacturing capacity. There are currently 40 people employed on-site.

### Current Non-Compliance Risk

The HCI effluent is an aqueous, highly saline, organic, batch discharge of maximum volume. 50 cubic metres per day. There is no request to increase the daily effluent volume with this IPPC consent. The daily concentration limits on the company's effluent discharge consent ( particularly COD / BOD concentrations ) have become the bottleneck for site development. The current consent allows a population equivalent of 1,667 per day ( equivalent to 100 Kg.



BOD per day ) which is in the small to medium category for the pharmaceutical sector. IPPC also requires conservation and recycling of water on-site which causes increases in licence parameter concentrations.

The risk of non-compliance with a concentration based ELV for COD is therefore high when the company expand their production spectrum.

### Processes

Cleaning In Process ( CIP ) will continue to give rise to most of the trade effluent volume as follows :

- between batch products
- between different intermediate products
- between same intermediate products

Currently trade effluent is pH neutralised and balanced prior to batch disposal to sewer. Dilution of the final effluent with mains water ( a previous compliance option ) is very much against the spirit of IPPC.

### Best Available Technology

The IPPC Directive requires that Best Available Technology ( BAT ) be used to treat wastewater effluent streams. The most recent Bref note for BAT for the Manufacture of Fine Chemicals ( issued December, 2005 ), includes both wastewater treatment on-site and off-site in municipal wastewater treatment works. Fine chemicals include pharmaceutical products manufactured via both chemical and biological processes. Because of the high saline nature of HCl's effluent stream, biological ( secondary ) treatment cannot be carried out successfully on site. Combined on-site and off-site treatment of the much diluted effluent at the Ringsend plant appears to be acceptable by the EPA as BAT ( personal communication from Inspector Breen Higgins – 22/03/06 ). Other aspects which must be considered in deciding on BAT for individual facilities include cross media effects, economics and applicability ( site size considerations etc.).

Section 5.1.2.5.1 of the Bref specifically addresses mother liquors with high salt content and advises that they be avoided completely or that alternative separation techniques be individually considered for use. Both of these options occur at the production planning and design stage rather than the effluent treatment ( end of pipe ) stage and may be difficult to retrofit in an existing plant ( not economically viable ).

Section 5.2.4.7.1 of the Bref states that “ BAT must ensure that elimination ( of COD ) in a joint ( municipal ) wastewater treatment plant is not poorer than the case of on-site treatment.” This is definitely the case at HCl, where on-site biodegradation cannot occur due to high salinity and biodegradation takes place at Ringsend.

The combination of on-site and off-site BAT implemented at HCl therefore appears to fulfil the recommendations of the Bref.

### Effluent Toxicity at Ringsend

HCl have provided a report by Enterprise Ireland ( 24/01/06 ) on effluent toxicity to activated sludge ( inhibition of Ringsend sludge respiration rate ). ISO toxicity test 8192 (Test Method B) was carried out using HCl effluent. Results show an inhibition threshold of 1% – 2% v/v of HCl effluent in Ringsend activated sludge. The inhibition threshold represents the cutoff concentration that effluent has no detectable inhibition impact. The EC<sub>50</sub> was 10% - 20% v/v HCl effluent in Ringsend activated sludge. Given that the exposure of activated sludge at Ringsend is orders of magnitude less than this ( maximum of 0.0125%v/v ), toxicity effects can be assumed negligible at the Ringsend WWTP. This is based on a volume of HCl effluent of 50 cubic metres per day in a dry weather flow influent at Ringsend of approximately 400,000 cubic metres per day.

### **Freshwater Aquatic Toxicity**

Overflows of HCl effluent occurring from the sewer en-route to Ringsend are more risky in terms of freshwater aquatic toxicity in local receiving surface or groundwaters where there is low dilution of salinity. Aquatic toxicity tests were included as a condition in the previous consent to acquire baseline data for this scenario. It is recommended that Fingal County Council carry out a desk top risk assessment based on effluent dilutions available locally in the foul sewer at Damastown and in the Grand Canal Tunnel sewer. The River Tolka catchment is the receiving surface water catchment in the event of a foul sewer overflow. The vulnerable overflow points ( if any ) should be identified.

Chemical and monitoring conditions are attached for the consent based on an unchanged daily effluent volume of **50 cubic metres** as advised by Mr.Jim Kavanagh, Water Pollution Inspector, Swords.

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