ATTACHMENT No. F

- Cambrex Safety Statement
- Cambrex Emergency Operational Procedure
- Cambrex Major Accident Prevention Policy
- Drawing IPC 126, Location Plan of Bunded Areas
- Drawing IPC 111, Process Drains Layout
- Drawing IPC 112, Process Area Surface Drains (PASD) Layout
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DOCUMENT PART 1

SAFETY MANAGEMENT CONTROL DOCUMENT

SECTIONS 1 TO 2
(INCLUDING APPENDICES)
THE SAFETY STATEMENT CONSISTS OF TWO DOCUMENTS WHICH ARE INTENDED TO BE USED IN CONJUNCTION WITH EACH OTHER

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This Statement may not be re-produced outside the organisation or its corporate body in any way without the prior written permission of Cambrex Cork Limited and may not be given to a third party with the exception of the Health and Safety Inspectorate.

This document is intended to assist in reducing the possibility of accidents and ill health, by bringing to the attention of the organisation identified hazards and associated risks levels. Within the constraints of time and resources available, every effort has been made to identify all hazards and recommend remedies. It is not intended to state that all other potential hazards be under control at the time of the hazard analysis and risk assessment.

The Safety, Health and Welfare at Work Act, 2005, which applies to all persons at work, requires every employer to produce a Safety Statement and to bring the Safety Statement to the attention of all employees. These documents set out the organisation Safety Management procedures and controls and are applicable to all its activities.

Our aim is to ensure a safe working environment at all times for both employees and others and to improve our safety standards where possible. This can only be accomplished by the persistent efforts of all of us.

While the company will do all that is reasonably practicable to ensure a safe and healthy working environment and in conjunction with the Safety, Health and Welfare at Work Act, 2005, responsibility for health and safety at work rests with the employee at all levels within the organisation, who have direct responsibility for their own safety and that of those around them. This Safety Statement will be revised on an ongoing basis by Management in order to ensure achievement of the overall objective, improve safety awareness and reduce accidents and ill health at the organisation. Safety and health within the organisation must be dynamic and must not become routine.
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- Acetylation
- Aromatic substitutions
- Condensation
- Cyanation
- Cyanation
- Grignard reaction
- Mannich reactions
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Currently Cambrex Cork Ltd has over twenty products in their portfolio and normally two to three new processes are added each year. All new processes that are introduced are subjected to various safety tests and checks to ensure that the processes are safe and comply with all relevant statutory provisions.

The current shift pattern is 3 x 12-hour shifts, five days per week.

Facilities at Cambrex
The plant is constructed on a 26 acre site, and comprises of the following main features:

- Administration / Quality Control Building: This building contains a reception area, offices, boardroom, Quality Control and Research & Development Laboratories.
- Process Buildings PB1 & PB2: These contain the main production plant reactor centrifuges, dryers and ancillary equipment. These plants are operated via a combination of manual and automatic control systems. They are currently used as multi-purpose facilities for the manufacture of bulk generic pharmaceuticals.
The Pilot Plant is incorporated into PB1. This is used for small-scale production and the development of new processes.

Utility and Maintenance Building: This building houses maintenance offices, a boiler house, workshops including an instrumentation laboratory, engineering equipment and spare parts required for the maintenance facility. It also houses the standby site generator, main electrical switch room and distribution system.

Finished Product Warehouse: This area is used for the storage of final products.

Drum Store Area: There are several partially covered and some enclosed buildings here used for the storage of drummed materials such as solvents, acids, alkalis, intermediates and wastes awaiting recovery.

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Water Pump House: This area contains the air compressor plant for the site, water and fire pumps and a nitrogen generation unit.

Tankfarm: This bunded liquid storage facility consists of bulk tanks for the storage of organic and inorganic liquids. These tanks contain either virgin solvents or wastes. Both PB1 and PB2 have tank farm areas.

Waste Water Treatment Plant: This consists of a biological wastewater treatment unit for the treatment of all potentially contaminated water from throughout the site together with surface waters from those areas where contamination could occur. The area consists of waste equalisation basin, aeration basins, clarifiers, air blowers, a sludge press unit, DAF unit and an associated control room.

Air Treatment Plant: This area consists of several packed scrubbing towers and associated liquor holding tanks and pumps. Contaminated air raising from processing operations is treated in these scrubbing towers. In addition to this, a thermal oxidiser is present to further treat the emissions from the scrubber.

Utility Building PB2: Contains nitrogen, air compressor, refrigeration unit and deionised water generation system.
The Safety Statement comprises of 2 sections, which are divided into two documents as follows.

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**LITTLE ISLAND,**  
**CORK, IRELAND**

**Phone:** 021-4978000  
**Fax:** 021-4353599  
**E-mail:** Cork@cambrex.com

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9.4 Fire crew leader
9.5 Fire crew

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10.3 Site Controller
10.4 Fire crew leader
10.5 Fire crew

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11.6 Fire crew

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14.1 General

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14.7 Automatic digi dialler

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APPENDICES

Appendix I Preparatory Actions

Appendix II Roles Emergency Response Team

Appendix III Incident Event Log

Appendix IV Emergency Telephone List

Appendix V Emergency Response Team room

Appendix VI Company Doctor surgery map

Appendix VII Staff Evacuation Lists

Appendix VIII Spillage absorbent equipment

Appendix IX Revision History
# MAJOR ACCIDENT PREVENTION POLICY

Cambrex Cork Ltd  
Little Island, Cork  
Ireland  
Phone: 021-4978900  
Fax: 021-4353589  
E-mail: cork@cambrex.com

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<tr>
<td>Timmy Carey [HSE Section]</td>
<td>Date:</td>
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<td>Approved By</td>
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<td>Sean Kenrick [Operations Manager]</td>
<td>Date:</td>
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<tr>
<td>Paudie Burke [Managing Director]</td>
<td>Date:</td>
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<td>Replacing</td>
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Policy document

SECTION B
Identification of Major accidents
POLICY

Under the European Union, Council Directive 96/82/EC on the control of accident hazards involving dangerous substances (‘Seveso II’ Directive) has been implemented into Irish Legislation. In association with its contents the Company’s major accident prevention policy is prepared with the objective of:

- Containing and controlling incidents so as to minimise the effects, and to limit damage to man and the environment and property.
- Implementing the measures necessary to protect man and the environment from the effects of major accidents.
- Communicating the necessary information to the public and to services or authorities concerned in the area.
- Providing for the restoration and the clean up of the environment following major accidents.

Cambrex Cork, will achieve its emergency preparedness objectives by adhering to the following process:

1. Prepare formal plans and procedures that address the events.
2. Select and train key individuals to respond in the event of an emergency.
3. Provide the resources necessary to facilitate an efficient and effective response.
4. Test and validate levels of emergency preparedness through the conduct of exercises.
5. Maintain, audit and review the Plan on a scheduled basis.
6. Appoint a custodian of the Plan and ensure that a record of amendments to the Plan is maintained.

Signed: 
Paudie Burke
Managing Director

Date: _____
ORGANISATION & PERSONNEL

It is management's responsibility to create and maintain an environment in which every individual employee is committed to health and safety improvement.

All levels of management share the responsibility, in conjunction with the Managing Director, to provide administrative support and to establish organisations and programmes to attain high operating safety standards within their respective areas of control.

Managers, Section Heads, Supervisors and the Safety Officer have special day to day responsibilities to give full consideration to the health and safety of all employees.

The MAPP should be communicated by personal example, by sincere concern and by providing training to all personnel in safety instruction, procedures and practices.

Managers and Supervisors must make all employees aware of the provisions of the Major Accident Prevention Policy and the contents of all written safety procedures relevant to ensure the effectiveness of same. This forms an integral part of the safety management system at Cambrex Cork, which is also reflected in the site's safety statement.

The management is ultimately responsible for safety within the organisation.

Roles & Responsibilities

The HSE Section Head will co-ordinate and review the MAPP for the facility by working with respective Managers, Supervisors and Safety Representatives.

If at any time any information contained within the MAPP is altered, the HSE Section Head is to be notified. This is reflected in the SOP HS036, which details key responsibilities involved in the management of major hazards.

HSE Section Head
- Identify all major accidents on site in conjunction with expertise site personnel and assess the extent and severity of the consequence of such accidents.

Operations Manager
- In conjunction with the Managing Director and Engineering Section Head ensure the provision and maintenance of installations within Cambrex Cork so far is reasonably practicable, without risk to man and the environment.

HSE Section Head
- In conjunction with all site Management the making of arrangements to ensure that the use, handling, storage and
<table>
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<th>Role</th>
<th>Responsibility</th>
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<tr>
<td>Management</td>
<td>The provision of information, instruction, equipment, training and supervision as is necessary to ensure so far is reasonably practicable, the occupational safety and health of persons working in Cambrex Cork.</td>
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<tr>
<td>Management</td>
<td>The use of best practicable means to prevent a major emission into the environment from any part of the establishment of dangerous substances resulting from uncontrolled developments, and the rendering harmless of same.</td>
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<tr>
<td>HSE Section Head</td>
<td>On being notified by the competent Authority of being an establishment which may pose a risk to another establishment in light of the EU Directive, make contact with the relevant party and make available such documentation as the MAPP and emergency response procedures and policies in addition to any major accident hazards that have been identified which may pose a risk to such an establishment in addition to man and the environment.</td>
</tr>
<tr>
<td>Management/Section Head/Supervisors</td>
<td>To notify the HSE Section Head of any changes relevant and pertaining to the contents of the MAPP.</td>
</tr>
<tr>
<td>HSE Section Head</td>
<td>To prepare, develop and implement a MAPP in conjunction with site personnel to reflect current practices on site to ensure the protection from a major event occurring and if such an event occurs that suitable emergency preparedness is in place while conforming to statutory requirements;</td>
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</table>
| Operator of the Establishment (consisting of Managing Director, Managers, Section Heads, Supervisors) | - Prevent major accidents from occurring;  
- To limit the consequences of major accidents for man and the environment |
IDENTIFICATION AND EVALUATION OF MAJOR ACCIDENTS
Cambrex Cork operates to procedures for systematically identifying hazards arising from normal and abnormal operations and the assessment of their likelihood and severity consequences. This is primarily achieved in items listed, 1-3. In depth detail of major hazards is addressed with in SECTION B.

1. Hazard and Operability studies (HAZOP)

The technique is designed to identify hidden hazards, particularly plant deviations or misoperations that lead to unexpected hazards. The hazop study ensures that facilities, equipment, utilities, services and processes are designed and installed to provide safe and efficient operation.

The main aim of a Hazop study is to identify hazards. The team then recommends actions to remove or minimise these hazards.

Hazop is only one of a number of hazard identification techniques that are available. A Hazop is regarded as a comprehensive study which co-exists/compliments other studies such as chemical reaction hazard analysis, process safety review, electrostatic surveys, dust explosion protection/prevention assessment, checklists, codes of practice, corporate guidelines and quantitative risk assessment methods.

2. New Process Introduction Procedure (NPIP)

The purpose of this procedure is to ensure that the scale up of new processes at Cambrex Profarmaco, from the laboratory to the plant, is carried out in a safe environmentally sound and effective manner.

The procedure covers the transfer to the pilot plant or the main plant for initial manufacture, of new products and processes and the assessment for the manufacture in a routine basis. In order to fully comply with the current legislation, regulations and best practice of the Environmental Act 1990. This procedure assumes that an order has been received, and that the relevant information and approvals have been obtained, or that a modification to an existing process is deemed to require the “new process introduction procedure”

The New Process Introduction Procedure (NPIP) consists of four sections, each concerned with the scale up and technology transfer of new processes at Cambrex Profarmaco.
Refer to: R&D SOP 051- NPIP Section 1
R&D SOP 052- NPIP Section 2
R&D SOP 053- NPIP Section 3
R&D SOP 054- NPIP Section 4

The NPIP is designed to apply a structure to the methodology by which Cambrex Profarmaco implements the manufacture of new processes. The document is reviewed as part of the systematic introduction of the NPIP on an ongoing basis, involving a Project Team.