

Public Information on an upper-tier establishment as required by Regulation 25

Information on upper-tier establishments

All establishments subject to the *COMAH Regulations 2015* have submitted a notification in a standard form to the Authority. This includes information on their location, the hazard categories of the dangerous substances present with an indication of their dangers, emergency action information and sources of additional relevant information.

Additional information has been provided by upper-tier establishments, including details on the possible major accidents arising in the establishment and the action to take in the event of an emergency.

General Duties on Operators

Operators have a general duty to identify all the major accident hazards in their establishment, take all necessary measures to prevent major accidents and to limit the consequences of such accidents to human health and the environment.

Operators of upper-tier establishments are also specifically required to ensure that 'all persons likely to be affected' by a major accident originating at the establishment receive clear and intelligible information on safety measures and on what they should do in the event of a major accident. This information must be directly supplied to all buildings and areas of public use, including schools and hospitals and, in the case of domino groups, to all neighbouring establishments.

Information on emergency plans

Information on external emergency plans may also be available from the Local Authority, the Gardaí and the Health Services Executive.

Public information for an upper-tier establishment

This establishment is subject to the COMAH Regulations 2015 and has submitted a notification to the Authority.

The following information, which has been extracted from the notification, fulfils the requirements of Regulation 25(3)(a).

The date of the most recent COMAH inspection (added by the Central Competent Authority) can also be found in the table below.

Notification History

Pfizer Ireland Pharmaceuticals

Version	Reason	Date
1.0	Mandatory notification	31/05/2016
2.0	Information update	29/11/2017
3.0	Information update	01/11/2018
4.0	Information update	13/11/2019
5.0	Information update	21/12/2020
6.0	Information update	06/01/2022
7.0	Information update	02/03/2023
8.0	Information update and company name change	05/12/2024

Regulation 25 information for Pfizer Ireland Pharmaceuticals

Operator Name	Registered Name	Pfizer Ireland Pharmaceuticals Unlimited Company
	Trade Name	Pfizer Ireland Pharmaceuticals
Establishment Address	Address	Active Pharmaceutical Ingredients Plant, P.O. Box 140, Ringaskiddy
	County	Cork
	Eircode	P43 X336
Notification Details	Tier	Upper-tier
	Activity	Production of pharmaceuticals
Dangerous Substance information	Hazard Categories / Named Substances	E1 Hazardous to the Aquatic Environment, E2 Hazardous to the Aquatic Environment, H1 Acute Toxic Cat.1, H2 Acute Toxic Cat.2, H3 STOT Toxic Cat.1, O1 Substances or mixtures with hazard statement EUH014, O2 Substances and mixtures which in contact with water emit flammable gases, P2 Flammable gases, P5a Flammable Liquids, P5c Flammable Liquids, P7 Pyrophoric Liquids and Solids, Acetylene, Hydrogen, Hydrogen Chloride, Methanol
	Dangerous Characteristics / Hazard Statements	EUH014, H220, H224, H225, H226, H250, H260, H300, H310, H330, H331, H370, H400, H410, H411
Emergency Information	How the public will be warned	The public likely to be affected will be warned by one or more on-site sirens.
	Behaviour to take in event of major accident	As we are an upper-tier establishment, we send leaflets to the persons who are likely to be affected, which includes this information.
	Additional Information	
Inspection	Most recent COMAH Inspection (updated)	9 th October 2024

	quarterly):	
	Where more detailed information on inspection available	More detailed information about the inspection and the related inspection plan can be obtained upon request, subject to the requirements of Regulation 26, from: CCPS unit, Health & Safety Authority, Metropolitan Building, James Joyce Street, Dublin 1.
Information	Where further relevant information available	Further information about this establishment may be obtained, in the first instance, from the operator. www.pfizer.ie Subject to Regulation 26 ('Access to information and confidentiality') information may also be available from the Health and Safety Authority, on request, under the Access to Information on the Environment Regulations.

Nature of major hazards (1)	Nature of major accident	Release of dangerous substances with potential for adverse health effects.
	Potential human health effects	Substantial exposure to toxic chemicals (potentially fatal)
	Potential environmental effects	Inhalation, ingestion or direct contact with dangerous substances causing harm to specific species of animals. Direct contact with dangerous substances causing harm to specific species of plants.
	Scenario details	Release of AHCL The scenarios identified that would result in a release of toxic gas are; 1. Cold Catastrophic failure of the HCl cylinder 2. Leak from cylinder/pipework 3. Release from a pressure relief valve
	Control measures	Establishment has facilities to detect and manage releases of gases that may have harmful effects. All of the establishment's storage tanks, process vessels, pipe work and control systems are designed and maintained to an appropriate standard to prevent major accidents. Traffic management arrangements are in place. Isolation procedures are in place to prevent or reduce the extent of an incident. Emergency response system & procedures in place. There are slot drains around the perimeter of the HCl cylinder area to prevent accumulations of flammable liquid around the HCl cylinder. In addition, the cylinders are held on an elevated plinth. The HCl cylinder is protected from radiant heat emanating from a fire in the OSP 2 hydrogenation building (Building 168) by means of cladding on the northern elevation. The cladding is rated to provide at least 1 hour fire resistance (to BS476:20:1988). Schedule 40 piping is used. This robust piping is unlikely to fail catastrophically and would be expected to undergo external impact without failing.
	Onsite response	This establishment has prepared an internal emergency plan for major accidents which is tested at least every 3 years, has liaised with the emergency services and agreed on the actions and arrangements to deal with major accidents and minimise their effects.
	Offsite effects/action	A publicly available external emergency plan has been drawn up by the local authority, Gardaí and HSE to respond to any consequences outside this establishment as a result of a major accident.

Nature of major hazards (2)	Nature of major accident	Fire
	Potential human health effects	Temporary exposure to smoke from a fire from which generally fit and well people are unlikely to experience long-term health problems.
	Potential environmental effects	There are no potential consequences on the environment from the major accident hazards identified.
	Scenario details	Warehouse Fire which may result in the release of a smoke plume containing toxic combustion products evolved during a major fire at the on- site principal product storage warehouse (Building 164)
	Control measures	All relevant warehouses and storage facilities are fitted with fire detection and protection systems. Buildings on site are designed and arranged to prevent or minimise knock-on effects of an incident. An automatic surface water isolation valve is present on site Establishment has an automatic fire alarm system connected to a central monitoring station and/or the fire service. Delivery vehicles are not unloaded in the warehouses. The containment pond is sized by assuming a worst case incident in a production plant and the volume of potential run-off from this. Delivery vehicles are not unloaded in the warehouse. The containment pond was sized by assuming a worst case incident in a production plant and the volume of potential run-off from this.
	Onsite response	This establishment has prepared an internal emergency plan for major accidents which is tested at least every 3 years, has liaised with the emergency services and agreed on the actions and arrangements to deal with major accidents and minimise their effects.
	Offsite effects/action	A publicly available external emergency plan has been drawn up by the local authority, Gardaí and HSE to respond to any consequences outside this establishment as a result of a major accident.

Nature of major hazards (3)	Nature of major accident	Fire
	Potential human health effects	Temporary exposure to smoke from a fire from which generally fit and well people are unlikely to experience long-term health problems. Injuries caused by projectiles being ejected from the incident site.
	Potential environmental effects	No Effect
	Scenario details	Drum Store Pool Fire. Methanol was used as the model material Scenario 1: Pool Fire Scenario 2: Catastrophic Failure of an HCL Cylinder Scenario 3: Drum Projectile
	Control measures	All relevant warehouses and storage facilities are fitted with fire detection and protection systems. Buildings on site are designed and arranged to prevent or minimise knock-on effects of an incident. An automatic surface water isolation valve is present on site Establishment has an automatic fire alarm system connected to a central monitoring station and/or the fire service. Delivery vehicles are not unloaded in the warehouse. The containment pond was sized by assuming a worst case incident in a production plant and the volume of potential run-off from this. The drum warehouse floor is sloped to internal drains within each area i.e. a spillage of flammable liquid would not extend to the gas cylinder storage area.
	Onsite response	This establishment has prepared an internal emergency plan for major accidents which is tested at least every 3 years, has liaised with the emergency services and agreed on the actions and arrangements to deal with major accidents and minimise their effects.
	Offsite effects/action	A publicly available external emergency plan has been drawn up by the local authority, Gardaí and HSE to respond to any consequences outside this establishment as a result of a major accident.