

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

MSD Ireland (Ballydine)

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	16/12/2019
5.0	Information update	29/09/2020
6.0	Information update	13/10/2021
7.0	Information update	02/03/2023
8.0	Information update	29/06/2023

Regulation 25 information for MSD Ireland (Ballydine)

Operator Name	Registered Name	MSD Ireland (Ballydine)
	Trade Name	MSD Ireland (Ballydine)
Establishment Address	Address	Ballydine, Kilsheelan, Clonmel
	County	Tipperary
	Eircode	E91 V091
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, H3 STOT Toxic cat. 1, O2 Substances and Mixture which in contact with water emit flammable gases, P5a Flammable Liquids, P5c Flammable Liquids, P7 Pyrophoric Liquids and Solids, Anhydrous Ammonia, Hydrogen, Methanol
	Dangerous Characteristics / Hazard Statements	H220, H224, H225, H226, H250, H260, H300, H301, H310, H330, H331, H370, H400, H410, H411
Emergency Information	How the public will be warned	As we are an upper-tier establishment, we send leaflets to the persons likely to be affected, which includes this information. The public who may 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 likely to be affected, which includes this information.
	Additional Information	
Inspection	Most recent COMAH Inspection (updated quarterly):	2 nd May 2023
	Where more detailed information on inspection	More detailed information about the inspection and the related inspection plan can be obtained upon request, subject to the requirements of Regulation 26, from:

	available	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. http://www.msd-ireland.com/about-us/48/ballydine 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	Fire and Explosion and Release of dangerous substances with potential for adverse environmental effects.
	Potential human health effects	Injuries caused by projectiles being ejected from the incident site. Potential for burns to body.
	Potential environmental effects	Dangerous substances contaminating groundwater if containment fails. Dangerous substances discharged to sewer, passing through the sewage treatment works, being discharged into freshwater or estuarine waters and causing harm to the aquatic environment.
	Scenario details	Release of liquid solvent from tank in solvent recovery unit, evaporation & ignition (vapour cloud explosion). There are no significant off-site human health impacts associated with this scenario.
	Control measures	All of the establishments storage tanks, process vessels, pipework and control systems are designed and maintained to an appropriate standard to prevent major accidents. Key operating units and storage facilities have containment systems in place to keep chemicals and firewater on-site. Potential ignition sources are eliminated in accordance with the ATEX Directive to protect against the ignition of flammable material. Key operating units and storage facilities are fitted with fire detection and suppressant systems. Central computer control of processes (DCS System); Pipework located with limited access by forklift truck; Piping material specification; Visual inspection of overhead solvent lines during operations; Elevated pipe tracks; Flexible hoses on a Mechanical Integrity inspection program and replaced as needed; Operator in close attendance – manned activity; Solvent line blown with nitrogen (N2) after transfer; ATEX Zoning & Signage in place; All tanks are electrically bonded; Vehicle entry permit system; High level alarms in columns and tanks; Merck Corporate equipment standards for process vessels and bulk tanks; Operator training; Preventative maintenance; Use of qualified vendors of pumps; Batch sheets; High level interlocks (tanks / columns); Standard operating procedures; Procedure for formal hand back between Manufacturing and Maintenance Depts. following maintenance activity; Process Hazard Analysis; Process safety checks on streams sent to SRU; LEL detection (local alarm and DCS link); hand held extinguishers; automatically activated deluge system; 340 m2 kerbed area at SRU; drainage from bund to process drainage system; perimeter drains on building floor to take spillage away to process sewer; fire alarm / break glass units; operation is in open air location; fire truck, fire crew and emergency response equipment; foam supplies (1,100 l); fire hydrants (H1, H2); the Internal Emergency Plan for Ballydine contains a specific section detailing emergency response for pool fires at the site; main response would be to apply foam to the kerbed area to extinguish fire and prevent re-ignition; additional response would be to cool nearby tanks, cylinders and piperacks.

	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. You should cooperate with the instructions of the emergency services.

Nature of major hazards (2)	Nature of major accident	Fire and Release of dangerous substances with potential for adverse health effects. Release of dangerous substances with potential for adverse environmental effects.
	Potential human health effects	Breathing air with high concentrations of dangerous substances that could lead to asphyxiation and/or poisoning, which could result in fatal consequences. Very dense smoke may cause irritation of the lining of the air passages (nose, throat and lungs) the skin and the eyes.
	Potential environmental effects	Dangerous substances contaminating groundwater if containment fails. Dangerous substances discharged to sewer, passing through the sewage treatment works, being discharged into freshwater or estuarine waters and causing harm to the aquatic environment.
	Scenario details	Fire in Dry Warehouse No. 1 or 2: loss of containment of a closed drum of flammable and/or pyrophoric material followed by ignition. All firewater or resultant spillages would be routed to the process sewer for containment and treatment; no contamination of ground water is anticipated. Primary effects on human health would arise in the vicinity of the warehouse. Off-site impacts may necessitate the activation of the external emergency plan.
	Control measures	Suitable arrangements are in place to prevent or minimise loss of containment of dangerous substances. Key operating units and storage facilities have containment systems in place to keep chemicals and firewater on-site. Establishment has an automatic fire alarm system connected to a central monitoring station and/or the fire service. Incompatible materials are segregated and stored separately. Inspection of drums and cylinders prior to acceptance on site; training for forklift truck operators; Standard Operating Procedures (SOPs) for forklift operation; dedicated SOP for Dry Warehouse activities; smoke detection; LEL detection (Dry Warehouse 2); Flame detection; fire alarms; toxic gas detection / alarms (Dry Warehouse 2); drums and cylinders for hazardous materials conform with appropriate UN performance tested packaging specifications; steel rails to prevent impact from forklift trucks on cylinders; forced ventilation (Dry Warehouse 2); handling operations are manned - operator in close attendance; ATEX Zoning & Signage in place; signage outside building to inform personnel of the contents of the Dry Warehouse; building is earthed; operator training; planned maintenance for safety systems; retention bunds – Dry Warehouse No. 2 is fitted with a central floor grill to direct any spillages to underground collection sumps; preventative maintenance checks on warehouse racking; segregation of chemicals matrix in place which specifies which materials can be stored in Dry Warehouses; no other material is stored within 3 m of sodium methoxide (when present). Automatic dry powder system (Dry Warehouse 2); fire extinguishers (hand held); pre-action dry sprinkler system (Dry Warehouse 2); toxic and pyrophoric materials are

		separated by a fire wall (Dry Warehouse 2). Floor of building is sloped to collect any spillages in separate areas; fire alarm / break glass units; fire truck, fire crew and emergency response equipment; foam supplies; building is fitted with explosion relief panels (Dry Warehouse 2). The Internal Emergency Plan contains a specific section detailing emergency response for warehouse fires at the site.
	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. You should cooperate with the instructions of the emergency services.

Nature of major hazards (3)	Nature of major accident	Release of dangerous substances with potential for adverse health effects. Release of dangerous substances with potential for adverse environmental effects.
	Potential human health effects	Airborne material that can cause burning of the eyes and, if inhaled the throat, coughing or breathing difficulties. Breathing air with high concentrations of dangerous substances that could lead to asphyxiation and/or poisoning, which could result in fatal consequences.
	Potential environmental effects	Direct contact with dangerous substances causing harm to specific species of plants. Dangerous substances contaminating groundwater if containment fails.
	Scenario details	Spill of compressed liquefied gas with evolution of toxic vapours: loss of containment from a cylinder of boron trichloride followed by the evolution of hydrogen chloride to atmosphere. Primary effects on human health would arise in the vicinity of the release. Off-site impacts may necessitate the activation of the external emergency plan.
	Control measures	Chemical spillage prevention systems are in place. Detectors are in place to alert staff to any loss of containment. Access to the site is strictly controlled. Establishment has on-site response facilities to reduce the impact of an incident. All forklift truck drivers are appropriately trained; Standard Operating Procedure (SOP) for forklift truck operations; BCl3 cylinders are banded to pallets; the storage cylinders are robust and are certified to UN / ADR standards; fork lift cylinder cradles for transport; cylinders in storage are regularly checked for corrosion – daily check on warehouses; a purpose built charge station is used for charging BCl3 to factory, charge booth is fitted with a HCl detector to warn persons outside of a leak; BCl3 pipeline is all welded, thick walled stainless steel tubing; formal walk-down inspection & recording of appearance of pipelines containing highest hazard materials; pressure testing of line before campaign; pressure tests on piping are documented & signed off following repair / maintenance; structural protection along exposed sections of BCl3 pipeline; pipeline does not cross roadways; standard operating procedures are used; MSD site labelling system; batch sheet check for corrosion/integrity before transfer of BCl3; process safety training; Process Hazard Analysis, including Layer of Protection Analysis (LOPA); preventative maintenance; procedure MM-02 reflects control on storage duration limits for high hazard materials. Internal Emergency Plan contains detailed specific response sections dealing with releases of BCl3 at the site; cylinder valve size limits release rate; charge booth is fitted with a locally actuated emergency vent from the BCl3 cylinder head space into the caustic scrubber; the charge booth is fitted with extract ventilation to direct any leaks from inside the booth to a caustic scrubber; emergency eye baths / chemical showers located close to the potential locations for this major accident scenario; response team's resources include a dedicated spill response vehicle and a fire truck;

		<p>spill response vehicle equipment includes vapour suits, gloves and soda ash; fire truck contains SCBA, water spray monitors, hoses, nozzles and adapters; signs showing the location of breathing air stations.</p> <p>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.</p>
	Onsite response	<p>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.</p>
	Offsite effects/action	<p>You should cooperate with the instructions of the emergency services.</p>