



Telephone: 1890 289 389 Website: <http://www.hsa.ie>

## **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.



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## Notification History

### Novartis Ringaskiddy Ltd.

Version	Reason	Date
1.0	Mandatory notification	31/05/2016
2.0	Information update	30/11/2017
3.0	Information update	31/01/2019
4.0	Information update	13/11/2019
5.0	Information update	21/12/2020



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### Regulation 25 information for Novartis Ringaskiddy Ltd.

<b>Operator Name</b>	Registered Name	Novartis Ringaskiddy Ltd.
	Trade Name	Novartis
<b>Establishment Address</b>	Address	Ringaskiddy
	County	Cork
	Eircode	P43 FR63
<b>Notification Details</b>	Tier	Upper-tier
	Activity	Production of pharmaceuticals
<b>Dangerous Substance information</b>	<a href="#">Hazard Categories</a> / Named Substances	E1 Hazardous to the Aquatic Environment, E2 Hazardous to the Aquatic Environment, H1 Acute Toxic Cat.1, H3 STOT Toxic Cat. 1, O1 Substances or mixtures with hazard statement EUH014, P5a Flammable Liquids, P5b Flammable Liquids, P5c Flammable Liquids, P8 Oxidising Liquids and Solids, Methanol
	Dangerous Characteristics / <a href="#">Hazard Statements</a>	EUH014, H225, H226, H271, H301, H330, H331, H370, H400, H410, H411,
<b>Emergency Information</b>	How the public will be warned	As we are an upper-tier establishment, we send leaflets to the persons who are 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 who are likely to be affected, which includes this information.
	Additional Information	
<b>Inspection</b>	Most recent COMAH Inspection (updated quarterly):	30 <sup>th</sup> September 2020
	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.
<b>Information</b>	Where further relevant information available	Further information about this establishment may be obtained, in the first instance, from the operator. <a href="http://www.novartis.ie">www.novartis.ie</a> 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.



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<b>Nature of major hazards (1)</b>	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.
	Potential environmental effects	Inhalation, ingestion or direct contact with dangerous substances causing harm to specific species of animals.
	Scenario details	Release of toxic gas (Hydrogen Chloride)
	Control measures	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. Suitable arrangements are in place to prevent or minimise loss of containment of dangerous substances. Detectors are in place to alert staff to any loss of containment. Emergency response systems & procedures are in place. Inventory is split and segregated to minimise the quantity for release; HCl detectors, automatic shut-off valves and deluge system to minimise release; Connecting hoses are changed every six months; Automated transfer, which stops on high transfer rate; Pressure testing of lines and equipment; Non-destructive testing (NDT) to ensure integrity of pipework; High level of training and expertise of operators; Fire crew available 24 / 7; The worst case release scenario requires the catastrophic failure of a gas cylinder that is designed, manufactured and tested to meet the requirements of the international transportation of dangerous goods i.e. ADR, IMDG, RID etc.
	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. In the unlikely event of a major accident there may be immediate harm from the dangerous substances involved. There may also be disruption arising from the actions of the emergency services e.g. road closures.



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<b>Nature of major hazards (2)</b>	Nature of major accident	Fire and Explosion
	Potential human health effects	Potential for burns to body. Injuries caused by projectiles being ejected from the incident site.
	Potential environmental effects	
	Scenario details	Extremely flammable Hydrogen fire / explosion
	Control measures	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. Suitable arrangements are in place to prevent or minimise loss of containment of dangerous substances. Buildings on site are designed and arranged to prevent or minimise knock-on effects of an incident. Detectors are in place to alert staff to any loss of containment. Buss Loop design which circulates into vessel head space gives a high mass transfer for Hydrogen onto the catalyst surface. Thus, lower pressure and temperatures are required than traditional autoclave vessels; Highly automated hydrogenation sequence with pressure test, purge sequences, high level of safety interlocks, flow, temperature and pressure fully controlled; Use of British Compressed Gases Association (BCGA) Code of Practice for storage of Hydrogen cylinders; Hardwired interlocks on reactor high temperature and pressure. Note there are two pressure probes to monitor and control pressure; Emergency stop pushbuttons located at various levels and locations; Relief valve on Hydrogen line to hydrogenator; All electrical equipment is suitably rated for use in a hydrogenation unit, i.e. suitable for use in Zone 1, Gas Group IIC (Hydrogen); Excess flow valve and flow meters with control valves on the inlet vessel minimise flow / accumulation of over pressurisation; Training program for operators
	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.  In the unlikely event of a major accident there may be immediate harm from the dangerous substances involved. There may also be disruption arising from the actions of the emergency services e.g. road closures.



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<b>Nature of major hazards (3)</b>	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	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 entering freshwater or estuarine waters and causing harm to the aquatic environment.
	Scenario details	Main warehouse fire toxic / eco-toxic
	Control measures	All relevant warehouses and storage facilities are fitted with fire detection and protection systems. Incompatible materials are segregated and stored separately. Emergency response systems & procedures are in place. 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. Warehouse management systems and site's safety management system ensure housekeeping and compliance to site and corporate standards; The Early Suppression Fast Response (EFSR) automatic sprinkler system is designed to the L1 fire protection standard, which is the highest standard possible; Firewater retention pond ensures that firewater does not contaminate the estuary; Safe work permit and control of ignition sources in the area; Access to the warehouse is limited to authorised personnel; No smoking permitted in warehouse areas; Effective on-site security arrangements minimise the likelihood of arson; External fire spread to the warehouse is prevented by the fire resistance (at least one hour) of the external walls of the warehouse; In order to disperse the smoke the roof contains 6 vents each 1.7m X 2.8m on fusible links which operate at 180°C. The vents may also be operated by remote manual control from outside the building 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.
	Onsite response	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.
Offsite effects/action	You should cooperate with the instructions of the emergency services.	