

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

Eli Lilly Kinsale Ltd

| 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 | 29/09/2020 |
| 6.0 | Information update | 13/10/2021 |
| 7.0 | Information update | 06/12/2021 |
| 8.0 | Information update | 02/03/2023 |
| 9.0 | Information update | 05/12/2024 |
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Regulation 25 information for Eli Lilly Kinsale Ltd

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| Operator Name | Registered Name | Eli Lilly Kinsale Limited |
| | Trade Name | Eli Lilly Kinsale Limited |
| Establishment Address | Address | Dunderrow, Kinsale |
| | County | Cork |
| | Eircode | P17 NY71 |
| Notification Details | Tier | Upper-tier |
| | Activity | Production of pharmaceuticals |
| Dangerous Substance information | Hazard Categories / Named Substances | E1 Hazardous to the Aquatic Environment, H2 Acute Toxic Cat 2 and 3, H3 STOT Specific Target Organ Toxicity, O1 Substances or mixtures with hazard statement EUH014, O2 Substances and mixtures which in contact with water emit flammable gases, O3 Substances or mixtures with hazard statement EUH029 P2 Flammable Gases, P4 Oxidising Gases, P5c Flammable Liquids, P6b Self-reactive substances and mixtures and organic peroxides, E1 Hazardous to the Aquatic Environment Cat 1, E2 Hazardous to the Aquatic Environment Cat 2, Hydrogen, LPG, Methanol, Oxygen, Petroleum Products (Diesel) |
| | Dangerous Characteristics / Hazard Statements | EUH014, EUH029 H220, H225, H226, H242, H260, H270, H300, H301, 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 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. Site information and information on response to potential site events is regularly communicated at neighbours meetings. Specific safety leaflets are provided |

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| | | to neighbours within specified area and at neighbours meetings. |
| | Additional Information | |
| Inspection | Most recent COMAH Inspection (updated quarterly): | 26 th August 2024 |
| | 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.lilly.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. |

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| Nature of major hazards (1) | Nature of major accident | Release of hazardous material. The potential effects of this scenario are confined to the plant site and are not expected to have any offsite effects. |
| | Potential human health effects | Airborne material that can cause burning of the eyes and, if inhaled the throat, coughing or breathing difficulties. Substantial exposure to toxic chemicals (potentially fatal). |
| | Potential environmental effects | There are no potential consequences on the environment from the major accident hazards identified. |
| | Scenario details | Release of hazardous material. The potential effects of this scenario are confined to the plant site and are not expected to have any offsite effects. |
| | 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. Establishment has facilities to detect and manage releases of gases that may have harmful effects. Isolation procedures are in place to prevent or reduce the extent of an incident. Establishment has on-site response facilities to reduce the impact of an incident. Additional Controls in place include Operational Controls: The site has implemented an extensive Safety Management System (including Auditing & Change Management Systems) and this is regularly inspected by HSA. Standard Operating Procedures (SOPs) are used to detail all operations and maintenance activities. All personnel working at the site are trained and qualified for their work tasks. Containers are stored in secure, controlled storage areas. Engineering Controls: Containers used for storage of hazardous materials are very robust design and comply with all Irish regulations & codes. Automated shutdown systems are available to shut off supply from the container in the event of an incident. Maintenance of Systems and Facility: High preventative maintenance standards and safety instrumented systems are employed. Emergency Preparedness: The site has an onsite fully trained Emergency Response Team available on shift. Shelter indoors instructions and community siren is in place. |
| | 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. |

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| Nature of major hazards (2) | Nature of major accident | Fire /Release of dangerous substances with potential for adverse environmental effects. |
| | 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 | Dangerous substances contaminating groundwater if containment fails. Dangerous substances entering freshwater or estuarine waters and causing harm to the aquatic environment. |
| | Scenario details | Solvent vessel fire. The potential effects of this scenario are confined to the plant site and are not expected to have any offsite effects. The following control measures are in place to ensure this event is prevented. |
| | Control measures | <p>Key operating units and storage facilities are fitted with automatic shutdown and isolation systems.</p> <p>Potential ignition sources are eliminated in accordance with the ATEX Directive to protect against the ignition of flammable material.</p> <p>Containment systems are in place for relevant work areas to minimise the loss of spilled material to the environment. 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.</p> <p>Operation Controls: The site has implemented an extensive Safety Management System (including Auditing and Change Management Systems) and this is regularly inspected by the HSA. Standard Operating Procedures (SOPs) are used to detail all operations and maintenance. All personnel working at the site are trained and qualified for their work tasks.</p> <p>Engineering Controls: All solvent storage vessels are equipped with level control and high level automated level shutdown. All solvent storage vessels are nitrogen inerted to protect against ignition of flammable material. Site has extensive storm drain system and a containment pond to contain all spilled material and firewater on site. Site containment pond automatically shuts valves at the pond on detection of spills.</p> <p>Maintenance of Systems and Facility: High preventative maintenance and safety instrumented systems are employed.</p> <p>Emergency Preparedness: Site solvent vessels protected by firewater and foam systems. Site is equipped with an automated fire alarm system that is connected to a central monitoring system and control room. The site has an onsite fully trained Emergency Response Team available on shift.</p> |
| | 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. | |

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| Nature of major hazards (3) | Nature of major accident | Fire and Explosion |
| | 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 | |
| | Scenario details | Dryer explosion. The potential effects of this scenario are confined to the plant site and are not expected to have any offsite effects. |
| | Control measures | <p>Overpressure prevention systems are in place as necessary. Potential ignition sources are eliminated in accordance with the ATEX Directive to protect against the ignition of flammable material. Procedures in place to identify and manage deviations from normal operating conditions. Establishment has on-site response facilities to reduce the impact of an incident. Additional Controls in place include</p> <p>Operational Control: The site has implemented an extensive Safety Management System (including Auditing and Change Management System) and this is regularly inspected by HSA. Standard Operating Procedures (SOPs) are used to detail all operations and maintenance. All personnel working at the site are trained and qualified for their work tasks.</p> <p>Engineering Control: Equipment is equipped with temperature control to maintain temperature at safe levels and shutdown process on high temperature. Equipment/Dryers are equipment with an inertion system and oxygen analysers to prevent ignition of flammable or combustible material.</p> <p>Maintenance of Systems and Facility: High preventative maintenance standards and safety instrumented systems are employed.</p> <p>Emergency Preparedness: The site has an onsite fully trained Emergency Response Team available on shift.</p> |
| | 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. |