



An tÚdarás Sláinte agus
Sábháilteachta Health and Safety
Authority

European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2023

Competent Authority Exemption 09/2024 Rev.1

Applicable To National Road Transport Only

Carriage of UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S. (Sirolimus)

The Health and Safety Authority, as Competent Authority appointed under Regulation 10 of the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2023, and in accordance with Regulation 5(4)(a), hereby exempts the relevant participants from ADR Chapters 4.1, 6.1, 6.5 and 6.6 with respect to the packaging used for the carriage by road of UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, liquid, N.O.S. (Sirolimus), 9, III.

Purpose

The provisions of this exemption permit the carriage of UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, liquid, N.O.S. (Sirolimus) from Novo Nordisk Ireland Ltd, Monksland Industrial Estate, Athlone, Co. Roscommon, to Pfizer Newbridge, Littleconnell, Newbridge, Co. Kildare in packaging that is not in compliance with ADR Chapters 4.1, 6.1, 6.5 and 6.6.

The transport operation shall comply with the supplementary provisions contained in this document.

1. The substance shall be carried in a steel vessel that is leakproof, sealed and pressure tested to a design pressure of 50psig, with a dimpled jacket for heat transfer with a design pressure of 100psig.
2. The vessel is strapped to a track bolted to the outer packaging on a dedicated pallet for transport, in compliance with 7.5.7.1 and EN12195-1:2010.
3. The quantity carried shall be no more than 70kg.
4. Spill containment kits shall be placed with the vessel in the outer packaging (Envirotainer). The quantity of absorbent material carried shall be sufficient to absorb the full load of the substance. A specific checklist shall be used to ensure that sufficient spill containment is in place.

5. In addition to the vessel, two samples (100ml) are carried in accordance with ADR special provision 375 within the outer packaging. The samples are packaged in a UN 4GV box with a liner and vermiculite. The packaged samples are placed within an arm of the vessel.
6. The vessel and outer packaging (Envirotainer) shall be marked and labelled in accordance with ADR Chapter 5.2.
7. All personal protective equipment as listed in the Safety Data Sheet for Rapamycin NanoCrystal Dispersion shall be carried in the vehicle for use in the event of an incident involving spillage of the substance. The driver shall carry a P3 mask as the appropriate means of respiratory protection.
8. Drivers performing each transport operation under this exemption shall be certified in accordance with ADR Chapter 8.2 and shall be provided with function specific training in the use of personal protective equipment listed in the Safety Data Sheet.
9. Loading operations at Novo Nordisk Ireland Ltd and unloading operations at Pfizer Newbridge shall be carried out by personnel trained in accordance with ADR Chapter 1.3.
10. In all other respects, the transport operations performed in accordance with this exemption will comply with the relevant requirements of ADR.
11. A copy of this exemption must accompany the transport documentation and shall be made available to anyone who has a legitimate interest in the transport operation.
12. Any incident resulting in loss of containment of a substance during the transport journey shall be reported immediately by the participant in control of the transport operation to:
Health and Safety Authority
The Metropolitan Building
James Joyce Street
Dublin 1
D01 K0Y8
Email: contactus@hsa.ie
Phone: 0818 289 389
13. The Authority may withdraw this exemption for failure to observe any of these conditions or for any other reason, which the Authority deems sufficient.

This exemption is effective immediately and expires on 31 March 2026.

Date: 17 December 2024



Conor O'Brien
Chief Executive Officer
Health and Safety Authority