



An tÚdarás Sláinte agus SábháilteachtaHealth  
and Safety Authority

## **European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2021**

### **Competent Authority Exemption 01/2023**

#### **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 2021, 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 Alkermes Pharma 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 however comply with the provisions contained in this document.

1. The substance shall be carried in a steel vessel that is leakproof, sealed and pressure tested to 70 psig, and bolted inside an outer container on a dedicated pallet for transport.
2. The quantity carried shall be no more than 70kg.
3. Spill containment kits shall be placed with the vessel in the outer container. 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.
4. 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.

5. 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.
6. Loading operations at Alkermes Pharma Ireland Ltd, and unloading operations at Pfizer Newbridge shall be carried out by personnel trained in accordance with ADR Chapter 1.3.
7. In all other respects, the transport operations performed in accordance with this exemption will comply with the relevant requirements of ADR.
8. 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.
9. 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](mailto:contactus@hsa.ie)  
  
Phone: 0818 289 389
10. 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 14 May 2024.

**Date:** 11 May 2023



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**Mark Cullen**  
**Interim Chief Executive Officer**  
**Health and Safety Authority**