

Safety data sheet

Novolin®R, Actrapid

1. Identification of the substance/preparation and of the company/undertaking

Revision: 13-03-2013/ FRSE
Replaces: 13-09-2011

Distributor:
Novo Nordisk A/S
External Environment
Novo Allé DK-2880 Bagsværd

Tel: +45 44 44 88 88 Fax: +45 44 49 05 55
Emergency telephone +45 44 42 00 00
Email adresse: compliance-team@novonordisk.com

2. Hazards identification

The product shall not be classified as hazardous according to (EC) No. 1272 / 2008, EU GHS/ CLP.

3. Composition/information on ingredients

REACH registration number	CAS No./ Einecs no.	Substances	Classification/ CLP-classification	w/w%
-	11061-68-0	Aqueous solution for injection containing Insulin human, recombinant	Not classified	-

Please see section 16 for the full text of R-phrases and H-phrases.

4. First aid measures

Inhalation

Remove to fresh air. If breathing is irregular, call a physician immediately.

Ingestion

When swallowed, seek medical attention if symptoms persist and show the physician the package insert. Do NOT provoke vomiting. Not expected to be active orally (hypoglycaemia).

Skin

Wash with soap and water. Seek medical attention if irritation develops.

Eyes

Flush eyes with water for 15 minutes. If irritation develops, seek medical attention.

Other information

If in doubt, contact the doctor or emergency room. Always carry this manual or label.

5. Fire-fighting measures

The product is not readily flammable and combustible. Avoid breathing vapors and flue gases - seek fresh air. Fire Fighting Extinguishing Media:
In case of fire use foam, waterspray, dry chemical or CO2.

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6. Accidental release measures

Use the same personal protective equipment as stated in section 8. Mop up spillage with a cloth. Dam spill and collect with sand, vermiculite or other absorbent material and place in suitable waste containers. For information on disposal please see item 13.

7. Handling and storage

Handling

See section 8 for information about precautions for use and personal protective equipment.

Storage

Keep refrigerated 2 to 8 °C (36 to 46 °F) but not in the freezer. Do not freeze. Must be kept in tightly original packings and store according to product instruction and to prevent degradation.

8. Exposure controls/ personal protection

Precautions for use

Work under effective process ventilation (e.g. local exhaust ventilation).

There must be access to running water and eye wash.

Respiratory protection

Not normally required.

Gloves and protective clothing

PVC gloves, nitril rubber or similar of greater protection are recommended for waste clean-up and manufacturing and packaging operations.

Eye protection

Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a risk of splashing.

Occupational exposure limits

Contains no substances subject to reporting requirements.

9. Physical and chemical properties

Appearance: Colourless liquid

Odour: cresol

Relative density: 1.005

Boiling point: 100 °C

pH (solution): 7.4

Chemical formula: C₂₅H₃₈N₆O₇S₆

Molecular weight: 5808 Dalton

10. Stability and reactivity

No known incompatibilities. No known hazardous decomposition products.

11. Toxicological information

Acute

Inhalation

Not investigated. Inhalation of sprit mist containing protein may cause sensitization.

Ingestion

Not expected to be active orally. Absorption is not expected. Ingestion may cause discomfort.

Skin contact

May cause irritation by the active substance or any of the excipients.

Eye contact

May cause irritation. Avoid contact with the eyes.

Risk of sensitization

Hypersensitivity to the active substance or to any of the excipients.

Long-term effects

Repeated dose studies in animals did not identify any target organ toxicity.

May cause damage to the reproductive system

Novolin® R, Actrapid, Insulatard indicate no adverse effects of insulin on pregnancy and no malformative or feto/neonatal toxicity.

May cause genetic damage

Proteins are not expected to have any genotoxic potential. None of the excipients in Novolin® R, Actrapid, Insulatard posses any genotoxic potential.

12. Ecological information

Do not discharge large quantities of concentrated spills and residue into drains.

13. Disposal considerations

The product is not hazardous waste.

It is recommended that large quantities of waste and waste disposed of through the local receiving station with the following specifications.

Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

14. Transport information

The product is not covered by the rules for the transport of dangerous goods by road and sea according to ADR and IMDG.

15. Regulatory information

Hazard designation: It has been assessed that the product shall not be classified according to (EC) No. 1272 / 2008, EU GHS/ CLP.

Contains

Aqueous solution for injection containing Insulin human recombinant

Supplemental information

None.

Chemical safety assessment

Chemical safety assessment has not been performed.

16. Other information

Restrictions on use

None.

Training requirement

No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

Sources used

Other information

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

Full text of the R-phrases that are stated in section 3.

No R-phrases.

Full text of the H-phrases that are stated in section 3.

No H-phrases.

Novo Nordisk A/S - External Environment - Vandtårnsvej 83 - DK2860 Søborg - Tel.: +45 44 44 88 88 (Made in Toxido®) UK