

Safety data sheet

Novolin® N

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

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2. Hazards identification

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

Additional information

Novolin N ® is a drug product and should be used in accordance with the instructions for use. The product is tested according to applicable regulations for pharmaceutical products. The product poses no unacceptable toxicological risks when used as intended.

3. Composition/information on ingredients

REACH registration number	CAS No./ Einecs no.	Substances	Classification/ CLP-classification	w/w%
-	99551-09-4	Human Insulin Isophane Suspension Injection (NPH) (recombinant DNA origin)	Not classified	-
<i>Please see section 16 for the full text of R-phrases and H-phrases.</i>				

4. First aid measures

Inhalation

Seek fresh air. Seek medical advice in case of persistent discomfort.

Ingestion

Rinse mouth thoroughly and then drink plenty of water. Seek medical advice in case of persistent discomfort.

Skin

Remove contaminated clothing. Wash the skin thoroughly with water and continue washing for a long time.

Eyes

Rinse immediately with water (preferably using eye wash) for at least 5 minutes. Open eyes wide. Remove any contact lenses. Seek medical advice if irritation persists.

Other information

When obtaining medical advice, show the safety data sheet or label.

5. Fire-fighting measures

The product is not readily flammable. Avoid breathing vapors and flue gases - seek fresh air.

Fire Fighting Extinguishing Media: In case of fire use foam, waterspray, dry chemical or CO₂.

6. Accidental release measures

Use the same personal protection as for item 8. Sweep/pick up spill and place in suitable waste containers. For information on disposal please see item 13

7. Handling and storage**Handling**

No known incompatibilities. No known hazardous decomposition products.

Storage

Before use: store in a refrigerator (2°C - 8°C). Do not store them in or too near the freezer section or cooling element. During use: do not refrigerate. Do not store above 25°C. Keep the vial in the outer carton in order to protect from light. Protect from excessive heat and sunlight.

8. Exposure controls/ personal protection**Precautions for use**

Work must be done with effective mechanical ventilation (e.g. local extractor fan). There must be access to running water and eye wash.

Respiratory protection

Not required.

Gloves and protective clothing

PVC gloves, nitril rubber or similar protection are recommended for waste clear-up and manufacturing operations.

Eye protection

Wear safety goggles if there is a risk of eye splash.

Occupational exposure limits

Contains no substances subject to reporting requirements.

9. Physical and chemical properties

Appearance: Cloudy, white, aqueous suspension with a smell of cresol/
phenol (preservative)
pH (solution): 7.4 (at 20 °C)
Relative density: 1.005 (at 25 °C)
Boiling point: 100 °C
Chemical formula: C₂₅₇H₃₈₃N₆₅O₇₇S₆
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, Novolin N contains metacresol, which may cause allergic reactions.

Long-term effects

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

May cause damage to the reproductive system

Novolin® N 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® N posses any genotoxic potential.

12. Ecological information

Avoid discharge to drain or surface water.

13. Disposal considerations

The product is not hazardous waste under the Waste Decree.

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 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

Human Insulin Isophane Suspension Injection (NPH), (recombinant DNA origin)

Supplemental information**Chemical safety assessment**

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.

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