

Safety data sheet

Novolog® 10 ml vial, Novolog®FlexPen, Novolog® PenFill® cartridge

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 No special risk if used in accordance with the instructions of the supplier.

3. Composition/information on ingredients

REACH registration number	CAS No./ Eines no.	Substances	Classification/ CLP-classification	w/w%
-	116094-23-6	Aqueous solution contains insulin aspart. (Recombiant B28 Asp. Insulin)	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

Extinguish with powder, foam, carbon dioxide or water mist. Do not inhale vapours and flue gases - seek fresh air.
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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

Please see item 8 for information on personal protection.

Storage

NovoLog® must be kept in tightly closed original packings in a well ventilated place.

Before opening: Store in a refrigerator (2°C - 8°C). Do not freeze.

During use or when carried as a spare: Store below 30°C. Do not refrigerate. Do not freeze.

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: Colourless, clear liquid with a smell of cresol/ phenol (preservative)

pH (solution): 7.4 (at 20 °C)

Relative density: 1.005 g/ml (at 25 °C)

Boiling point: 100 °C

Chemical formula: C₂₅₆H₃₈₁N₆₅O₇₉S₆

Molecular weight: 5825.8 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 is not known to cause health effects.

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. Novolog 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

Novolog® indicate no adverse effects 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 Novolog® posses any genotoxic potential.

12. Ecological information

Avoid discharge to drain or surface water.

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 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

Contains insulin aspart. (Recombiant B28 Asp[rDNA origin])

Supplemental information

None.

Chemical safety assessment

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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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