

Safety data sheet

PenFill® cartridge Test Medium

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

Prepared on: 11-02-2013/ FRSE

Product use: For demonstration use

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.

Additional information

Not classified. For demonstration use. Test Medium is void of active drug. It is not for treatment and not for patients. Always inject test medium solution into a test object. Test medium should not be injected into skin.

For more information is recommend to refer to the package insert, which is intended for Health Care Providers.

3. Composition/information on ingredients

REACH registration number	CAS No./ Einecs no.	Substances	Classification/ CLP-classification	w/w%
-	-	Aqueous solution for demonstration use Test Medium is void of active drug.	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

Rinse out mouth thoroughly with water and give plenty of water.

Do NOT provoke vomiting. Seek medical advice if symptoms persist.

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

7. Handling and storage**Handling**

The demonstration pen is prefilled and should be used only in combination with products that are compatible therewith and allow the prefilled pen to function effectively.

Storage

Keep refrigerated. Test Medium must be kept in tightly closed orginal packings.

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

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: clear, colourless solution

10. Stability and reactivity

Test medium is stable under normal circumstances.

11. Toxicological information

Acute

Inhalation

Not investigated. Inhalation of vapours may cause irritation to the upper airways.

Ingestion

Not investigated. Ingestion may cause discomfort.

Skin contact

May cause irritation by any of the excipients. Avoid contact with the skin.

Eye contact

May cause irritation by any of the excipients. Avoid contact with the eyes.

Risk of sensitization

Hypersensitivity to any of the excipients (Phenol).

Long-term effects

No special precautions. Test Medium is not known to cause adverse health effects.

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 demonstration use, Test Medium is void of active drug.

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