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SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: STEEN Solution™

MANUFACTURER

XVIVO Perfusion AB
Box 53015
Mässans gata 10
SE-40014 Göteborg
Sweden

+46 31 788 21 50 (For product information)
+46 31 788 21 50 (For emergencies)

2. HAZARD IDENTIFICATION

POTENTIAL HEALTH EFFECTS

EYES: No known effects

SKIN: No known effects

INHALATION: No known effects

INGESTION: No known effects

CHRONIC EFFECTS: No known effects

SUBCHRONIC EFFECTS: No known effects

REPRODUCTIVE HAZARDS: No known effects

CARCINOGENICITY INFORMATION: No known effects

MISCELLANEOUS: Causes a slippery surface when spilled. Dextran is classified as food additive in EU and USA.

3. COMPOSITION / INFORMATION ON INGREDIENTS

CHEMICAL NAME

Human Serum Albumin (HSA)
Dextran 40
Physiological salt solution

CAS NUMBER

70024-90-7

-See Section 8 for exposure guidelines and Section 15 for regulatory information

COMPOSITION COMMENT: Physiological salt solution containing human serum albumin (HSA) and Dextran 40. STEEN Solution™ is intended for assessment of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

4. FIRST AID MEASURES



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EYE CONTACT: After initial flushing, remove any contact lenses and continue flushing.

SKIN CONTACT: Non toxic. Rinse with water.

INHALATION: No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

INGESTION: None. Ingestion is not considered a potential route of exposure.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

COC Flash Point: STEEN Solution is not flammable

Autoignition Temperature: N/A

FLAMMABLE LIMITS IN AIR: LEL: N/A UEL: N/A

EXTINGUISHING MEDIA: Will not burn.

FIRE & EXPLOSION HAZARDS: Material will not burn.

6. ACCIDENTAL RELEASE MEASURES

SAFEGUARDS (PERSONNEL): Absorb liquid, clean and dry area to prevent slipping.

7. HANDLING AND STORAGE

RECOMMENDED STORAGE TEMPERATURE: + 2°C (35.6°F) minimum to + 8°C (46.4°F) maximum

HANDLING (PERSONNEL): Use care in handling and store in an upright position.

HANDLING (PHYSICAL ASPECTS): Keep from freezing. Do not store at room temperatures above 8° C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: No special ventilation requirements.

EYE/FACE PROTECTION REQUIREMENTS: None.

SKIN PROTECTION REQUIREMENTS: None.

RESPIRATORY PROTECTION REQUIREMENTS: None.

MISCELLANEOUS: None.

EXPOSURE GUIDELINES: No information available.

9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid

COLOR: Pale Yellow

ODOR: None

SOLUBILITY IN WATER: Complete



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10. STABILITY AND REACTIVITY

STABILITY: Stable

11. TOXICOLOGICAL INFORMATION

COMMENTS: STEEN Solution is a physiological salt solution containing human serum albumin and Dextran 40. The salts as well as dextran 40 has no toxicological properties.

Please note that STEEN Solution contains human serum albumin (HSA) which is derived from human blood.

12. ECOLOGICAL INFORMATION

COMMENTS: No information available

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Treat or dispose of waste material in accordance with all local, state/provincial, and national requirements.

14. TRANSPORT INFORMATION

PRODUCT LABEL: STEEN Solution

D.O.T. HAZARD CLASS: Non-Hazardous*

Transport cool (+2 - +8)

*DOT (Department of Transportation)

15. REGULATORY INFORMATION

COMMENTS:

STEEN Solution is approved as a **Medical Device**.

16. OTHER INFORMATION

REASON FOR ISSUE: Official

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APPROVED BY: Jenny Wennerberg

TITLE: QA Manager

APPROVAL DATE: 2016-02-02

SUPERCEDES DATE: 2015-09-03

ADDITIONAL MSDS INFORMATION: The data in this Material Safety Data Sheet relates only to the specific material designated herein.



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