



Title

## SDS – Perfadex with THAM

Document number

XVIVO-27-12232

Revision

2

Valid date

2016-02-02

Page

1 of 4

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** PERFADEX® with THAM

### 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:** Perfadex - No known effects.

THAM causes eye irritation.

**SKIN:** Perfadex - No known effects.

THAM can cause moderate injury (redding or swelling).

**INHALATION:** Perfadex - No known effects.

THAM causes respiratory tract injury.

**INGESTION:** Perfadex - No known effects.

THAM is irritating to mouth, throat and stomach.

**CHRONIC EFFECTS:** No known chronic effects.

**SUBCHRONIC EFFECTS:** No known subchronic effects.

**REPRODUCTIVE HAZARDS:** No known reproductive hazards.

**CARCIOGENICITY INFORMATION:** No known cancer hazards.

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

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### CHEMICAL NAME

Physiological salt solution

Dextran 40

THAM buffer

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

**COMPOSITION COMMENT:** Physiological salt solution containing Dextran 40. For organ perfusion and preservation. Buffered Perfadex has a physiological pH and is considered to have the same safety profile as Perfadex.



Title <b>SDS – Perfadex with THAM</b>			
Document number XVIVO-27-12232	Revision 2	Valid date 2016-02-02	Page 2 of 4

#### 4. FIRST AID MEASURES

##### EYE CONTACT:

**Perfadex:** After initial flushing, remove any contact lenses and continue flushing.

**THAM:** After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Get medical attention.

##### SKIN CONTACT:

**Perfadex:** Non toxic. Rinse with water.

**THAM:** Immediately flush skin with plenty of water for at least 15 minutes. Get medical attention if symptoms occur.

##### INHALATION:

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

**THAM:** If inhaled, remove to fresh air. Get medical attention if symptoms occur

##### INGESTION:

**Perfadex:** None. Non toxic.

**THAM:** If signs of toxicity occur, seek medical attention.

#### 5. FIRE FIGHTING MEASURES

##### FLAMMABLE PROPERTIES:

COC Flash Point: Perfadex 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):

**Perfadex:** Absorb liquid, clean and dry area to prevent slipping.

**THAM:** Avoid breathing vapor. Wear safety goggles. Protect skin and eyes from exposure.

##### INITIAL CONTAINMENT:

**Perfadex:** Flush with water.

**THAM:** Ventilate air of leak or spill.



Title

## SDS – Perfadex with THAM

Document number

XVIVO-27-12232

Revision

2

Valid date

2016-02-02

Page

3 of 4

### LARGE SPILLS PROCEDURE:

Dilute with water.

## 7. HANDLING AND STORAGE

**RECOMMENDED STORAGE TEMPERATURE:** Store below 30°C. Do not freeze.

**HANDLING (PERSONNEL):** Use care in handling /storage.

**HANDLING (PHYSICAL ASPECTS):**

**Perfadex:** Keep from freezing. Single use only.

**THAM:** Store in a tightly closed container. Store in well ventilated place.

## 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

**Perfadex:**

**FORM:** Liquid  
**COLOR:** Colorless  
**SOLUBILITY IN WATER:** Complete

**THAM:**

**FORM:** Liquid  
**COLOR:** Colorless  
**SOLUBILITY IN WATER:** Complete

## 10. STABILITY AND REACTIVITY

**STABILITY:** Both Perfadex and THAM are stable

## 11. TOXICOLOGICAL INFORMATION

Perfadex is a physiological salt solution containing Dextran 40. The salts as well as dextran 40 have no toxicological properties.

THAM has a pH of 9.2. Buffer capacity - buffer available for acid binding about 150 mmol per bottle (50 ml) - 1 ml = 3 mmol.



Title <b>SDS – Perfadex with THAM</b>			
Document number	Revision	Valid date	Page
XVIVO-27-12232	2	2016-02-02	4 of 4

## 12. ECOLOGICAL INFORMATION

**COMMENTS:** No information available

## 13. DISPOSAL CONSIDERATIONS

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

## 14. TRANSPORT INFORMATION

**PRODUCT LABEL:** PERFADEX with THAM

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

\*DOT (Department of Transportation)

## 15. REGULATORY INFORMATION

**COMMENTS:**

Perfadex with THAM is approved by the FDA as a **Medical Device**.

## 16. OTHER INFORMATION

**REASON FOR ISSUE:** Official

**PREPARED BY:** Elin Sjöqvist

**APPROVED BY:** Jenny Wennerberg

**TITLE:** QA Manager

**APPROVAL DATE:** 2016-02-02

**SUPERCEDES DATE:** 2013-02-05

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

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