

# SAFETY DATA SHEET

## PureSperm<sup>®</sup> SpeediKit

### 1.0 Identification of the Substance/Mixture and of the Company/Undertaking

Product Name: **PureSperm<sup>®</sup> SpeediKit**

Product Catalogue No: **PSSK-010**

PureSperm<sup>®</sup> SpeediKit contains a sterile colloid (PureSperm<sup>®</sup> Unilayer) and a sterile salt solution containing human serum albumin (PureSperm<sup>®</sup> Wash). For preparing human sperm by the single layer method for intra-uterine insemination for ten patients. Both products are already dispensed in borosilicate glass centrifuge tubes and are ready to use.

Manufacturer: **NidaCon International AB**, Flöjelbergsgatan 16B, SE-431 37, Mölndal, Sweden.  
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### 2.0 Hazards Identification

This product is classified as non-hazardous according to Dangerous Substances Directive 67/548/EEC, Dangerous Preparations Directive 1999/45/EC, CLP Regulation (EC) No 1272/2008 and US OSHA regulations.

Physical hazards: None established.  
Human health effects and symptoms of acute exposure: None established.  
Human health effects and chronic exposure: None established.

### 3.0 Composition/Information on Ingredients

Consists of colloids in a physiological salt solution (PureSperm<sup>®</sup> Unilayer) and physiological salt solutions containing human serum albumin (PureSperm<sup>®</sup> Wash).

### 4.0 First-Aid Measures

If inhaled: Remove from exposure. Transfer to fresh air. If discomfort persists, obtain medical attention.  
In case of skin contact: Wash off with an abundance of water and remove contaminated clothing.  
In case of eye contact: After initial flushing with physiological saline, remove any contact lenses. Flush thoroughly with physiological saline for 15 minutes. If discomfort persists, obtain medical attention.  
If swallowed: Rinse mouth with water and give water to drink. Never give water to unconscious person. Obtain medical attention if feeling unwell.

### 5.0 Fire-Fighting Measures

Suitable extinguishing media: Unlikely to burn  
Special fire or explosion hazards: None known  
Products of combustion: None known  
Special exposure hazards: None known  
Protective equipment for fire fighters: Use correct equipment applicable to primary cause of fire.

### 6.0 Accidental Release/Spill Measures

Personal precautions: Floors may be slippery  
Environmental precautions: Always follow the community, state or federal regulations.  
Clean-Up methods: Wipe up using appropriate absorbent material and dispose with normal laboratory refuse, according to community, state or federal regulations.

### 7.0 Handling and Storage

Incompatible materials: Not applicable.  
Storage conditions: Store at room temperature or if opened at +2° to +8°C.  
Handling Recommendation: Use care in handling. Use aseptic working techniques.  
Handling Precautions: Avoid inhaling, ingestion, and contact with eyes.

### 8.0 Exposure Control/Personal Protection

Exposure limit: Not established  
Ventilation requirements: Normal ventilation  
Respiratory protection: If dried down to powder form, use face mask when handling large quantities.  
Eye protection: Use safety goggles when handling large quantities.  
Skin protection: Use protection gloves when handling large quantities.

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## 9.0 Physical and Chemical Properties

### PureSperm® Unilayer

Appearance: White/beige transparent liquid

Acid/Base pH: 7.4-7.8

Relative Density (water=1): Approx. 1.1

Osmolality: 300-330 mOsm

Physical and Chemical Properties for both:

Odour:

Viscosity:

Freezing/Melting Point:

Boiling Point:

Flash Point:

Upper Flammable Limits (%):

Lower Flammable Limit (%):

Auto flammability (°C):

Vapour Pressure:

Percent Volatility:

Solubility in water:

### PureSperm® Wash

Appearance: Transparent liquid (light yellow)

Acid/Base pH: 7.3-8.5

Relative Density: Approx. 1.0

Osmolality: 290-300 mOsm

Odourless.

Physiological salt solution and colloid.

Approx. 0°C

Approx. 100°C

Not established.

Not applicable.

Not applicable.

Not applicable.

Not established.

Not established.

Already water solution.

## 10.0 Stability and Reactivity

Stability under normal conditions: Stable.

Explosive properties:

Hazardous decomposition:

Hazardous polymerization:

Incompatible materials to avoid:

None known

Thermal decomposition may yield oxides of carbon.

Will not occur.

Avoid contact with oxidizing agents (such as nitric acid.)

## 11.0 Toxicological Information

Product is essentially inert. No toxic or ill effects under normal operating conditions. LD<sub>50</sub> is not established for this product.

## 12.0 Ecological Information

No known adverse ecological effects

## 13.0 Disposal Considerations

According to applicable regulations for aqueous, physiological salt solutions, i.e., open container and flush contents with tap water via a drain into the sewage system according to local community, state or federal regulations. The glass bottles and paper cartons can be recycled without adverse problems in the recycled glass and paper system, respectively.

## 14.0 Transport Information

Non-regulated transport. Non-dangerous goods.

## 15.0 Regulatory Information

See hazards identification.

PureSperm

United States: 510 (k) K984172 United States: 510 (k) K002630

EU: EC Certificate 41311678

PureSperm Wash

## 16.0 Other information

Distributor in Australia/New Zealand:

Tek-Event Pty Ltd

P O Box 569, Round Corner NSW 2158, Sydney / Australia

Ph: 0409 100 952 or 0408 491 516

Email: info@tekevent.com

Website: www.tekevent.com

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