

SAFETY DATA SHEET

ProInsert™

1.0 Identification of the Substance/Preparation and of the Company/Undertaking

Product Name: **ProInsert™**

Product Catalogue No: **PI15-5**

A sterile (irradiated SAL-10⁻⁶) package of plastic devices optimized for the preparation of density gradients for the separation and purification of human sperm to be used in Assisted Reproduction Technologies (ART). ProInsert minimizes the risk of re-contamination when retrieving the sperm pellet.

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

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2.0 Hazard Identification

The 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

Hazardous ingredients: None established, no ingredients listed as carcinogens. ProInsert contains plastic centrifuge tube, screw cap (HDPE), a plastic pipette (Polypropylene) and a plastic centrifuge-tube insert (Styrolux). All components are contained in sterilised packages

4.0 First-Aid Measures

If inhaled:	Not applicable
In case of skin contact:	Not applicable
In case of eye contact:	Not applicable
If swallowed:	Not applicable

5.0 Fire-Fighting Measures

Suitable Extinguishing Media:	Carbon dioxide, dry chemicals or water spray
Special Fire or Explosion Hazards:	None known
Products of Combustion:	None known
Special Exposure Hazards:	May cause toxic gas when heated. Avoid inhalation/use gas mask
Protective Equipment for Fire Fighters:	Use correct equipment applicable to the primary cause of fire

6.0 Accidental Release/Spill Measures

Personal Precautions:	Not applicable
Environmental Precautions:	Always follow the community state or federal regulations
Clean-Up Methods:	Dispose of contaminated components with normal laboratory refuse, according to community, state or federal regulation

7.0 Handling and Storage

Incompatible Materials:	Avoid contact strong oxidizing agents
Storage Conditions:	Store at room temperature
Handling Recommendation:	None established
Handling Precautions:	Avoid high temperatures

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8.0 Exposure Controls/Personal Protection

Exposure limit:	Not established
Respiratory Protection:	Normal ventilation
Eye Protection:	Not applicable
Skin Protection:	Not applicable

9.0 Physical and Chemical Properties

Appearance: clear polypropylene/k-resin plastic	Upper Flammable Limits (%): not established
Odour: odourless	Lower Flammable Limit (%): not established
Acid/Base: not applicable	Autoflammability (°C): not established
Viscosity: not applicable	Vapour Pressure: not established
Freezing/Melting Point: not established/>130°C	Relative Density (water = 1): not applicable
Boiling Point: not established	Solubility in water: non-soluble
Flash Point: not established	Percent Volatility: not applicable
Osmolality: not applicable	

10.0 Stability and Reactivity

Stability under normal conditions:	Stable
Explosive Properties:	Not applicable
Hazardous Decomposition:	Thermal decomposition may yield carbon oxides
Hazardous polymerization:	Will not occur
Incompatible Materials to avoid:	Avoid contact with strong oxidizing agents

11.0 Toxicological Information

Toxicity: Product is essentially inert. No toxic or ill effects under normal operating conditions.

12.0 Ecological Information

No known adverse ecological effects.

13.0 Disposal Considerations

Waste Disposal: According to applicable regulations for polypropylene or k-resin plastic labware. All components can be recycled. After being used to decontaminate patient sperm samples, all components should be disposed of securely as with other pathogen-contaminated labware.

14.0 Transport Information

Transport Information: Non-regulated transport. Non-dangerous goods.

15.0 Regulatory Information

See hazards identification.
United States: 510 (k) K131145
EU: 241568-2017-CE-NOR-NA-PS

16.0 Other Information

The above information is given in good faith, being based on the latest knowledge available to NidaCon International AB. NidaCon International AB disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any incidental or consequential damage resulting from reliance on the information given above.