

Safety Data Sheet

DATE OF ISSUE: August 25, 2023

ISSUED BY PASCAL

Product Name:	Retrax[®] Gel FS (formerly Stat Gel[®])
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1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER	
Product Name:	Retrax [®] Gel FS
Product Use:	Topical hemostatic gel
Manufacturer Name:	Pascal International, Inc.
Address:	2929 Northup Way Bellevue, Washington 98004 USA
Emergency Telephone (Infotrac):	1-800-535-5053, 1-352-323-3500
Telephone:	1-425-827-4694, 1-800-426-8051
Fax:	1-425-827-6893

2. HAZARDS IDENTIFICATION	
GHS Classification & Label Elements:	
This product is not considered to be or to contain hazardous chemicals based on evaluations made by our company under the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals, the Regulation (EC) No 1272/2008 of the European Parliament and of the Council (CLP), and the OSHA Hazard Communication Standard, 29 CFR 1910.122 . No Classification or Label Elements are required.	
Label Elements:	None
Hazards not otherwise classified (HNOC)	None
Safety Phrases:	None

3. COMPOSITION / INFORMATION ON INGREDIENTS		
Chemical Entity (Components)	CAS No.	Proportion
Ferric Sulfate	010028-22-5	10-30%
Amorphous Silica	7631-86-9	1-5%
Glycerin	56-81-5	15-40%
Polyoxyethylene (20) sorbitan monooleate	<u>9005-65-6</u>	0.1-1%

4. FIRST AID MEASURES	
Inhalation:	N/A
Ingestion:	Induce vomiting. Seek medical assistance.
Skin:	Flush well with water for at least 15 minutes.
Eye:	Flush well with water for at least 15 minutes.
First Aid Facilities:	Seek Medical assistance for further treatment, observation and support if necessary.

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5. FIRE FIGHTING MEASURES	
Extinguishing Media:	Suitable extinguishing media for the surrounding fire should be used.
Specific Hazards:	None
Precautions in connection with fire:	Use of self-contained breathing apparatus is recommended. Wear protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES	
Emergency Procedures:	Keep personnel away from area. Contain spills.
Clean Up Procedure:	Clean area with soapy water.
Personal precautions:	Wear gloves

7. HANDLING AND STORAGE	
Handling:	Use original container.
Storage:	Store in cool, well-ventilated area.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Exposure Limits:	Not determined
Respiratory Protection:	N/A
Eye Protection:	Safety glasses/goggles
Hand Protection:	Protective gloves
Engineering controls:	Standard room ventilation

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance:	Amber Gel
Odor:	Slight iron odor
pH:	1.0 to 2.0
Vapor Pressure:	Not determined
Vapor Density:	Not determined
Relative Density:	Not determined
Boiling Point:	Not determined
Freezing / Melting Point:	Not determined
Solubility in Water:	Ferric Sulfate is highly soluble in water.
Specific Gravity:	Not determined
Flash Point:	Not determined
Flammability:	N/A
Upper/Lower Flammability:	N/A
Evaporation Rate:	Not determined
Viscosity:	≥ 55,000 cps

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10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under ordinary conditions of use and storage
Conditions to Avoid:	High Heat
Incompatible Materials:	Strong acids, strong bases, oxidizing agents
Hazardous Decomposition Products:	None known
Hazardous Reactions:	None known

11. TOXICOLOGICAL INFORMATION

Hazardous Ingredient:	Ferric Sulfate Mixture LD ₅₀ (orally) MICE: 3200 mg/kg
Routes of Exposure:	Refer to Section 4 of SDS
Acute & Chronic Hazards	None known

12. ECOLOGICAL INFORMATION

Ecotoxicity:	No known effects
Persistence and Degradability:	No information found
Bioaccumulative Potential:	No known effects
Mobility in Soil:	No known effects

13. DISPOSAL CONSIDERATIONS

Disposal Method and Containers	Empty containers may be disposed of in waste containers.
Special Precautions	Disposal should be carried out in compliance with federal, state, and local regulations.

14. TRANSPORT INFORMATION

Hazard Classification:	Not regulated
Hazchem code:	None allocated
Australian Classification Statement (ADG):	N/A
UN Number:	N/A
Proper Shipping Name:	N/A
Environmental Hazards:	None known
Special Precautions during transport:	None

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15. REGULATORY INFORMATION	
Precautionary Phrases:	For professional in-office use only. Keep out of reach of children.
AICS (Australia)	This product is a medical device and not subject to chemical notification requirements.
Poison Schedule:	None allocated
CA Prop 65:	No ingredients are subject to CA Prop 65 warning.
Note:	Refer to applicable international, national, and local regulations and provisions.

16. OTHER INFORMATION	
Legal Disclaimer:	Information contained in this SDS is based on data believed to be correct. This information does not purport to be all inclusive and shall be used only as a guide. No warranty is expressed or implied regarding the accuracy of this data or the results to be obtained from the use thereof. In no event will the manufacturer or the distributor be responsible for damages of any nature whatsoever resulting from the use of or reliance upon this information.
SDS History	
Date of Issue:	August 25, 2023
Replaces Issue:	February 12, 2020
Changes made to previous issue:	Updated issue date; Updated proportion percentages in section 3; Updated Australia AIC statement and added CA Prop 65 statement in section 15.