

DATE OF ISSUE: October 10<sup>th</sup>, 2025

ISSUED BY PASCAL

|                      |  |
|----------------------|--|
| <b>Product Name:</b> | Retrax <sup>®</sup> Gel FS (formerly Stat Gel <sup>®</sup> ) |
|----------------------|--|

## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

|                                   |  |
|-----------------------------------|--|
| Product Name:                     | Stat Gel <sup>®</sup>  |
| Product Use:                      | Topical hemostatic gel   |
| Manufacturer Name:                | Pascal International, Inc.   |
| Address:                          | 2929 Northup Way<br>Bellevue, Washington 98004<br>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   |
| New Zealand Importer/Distributor: | Ivoclar Vivadent Ltd.  |
| Address:                          | PO Box 303011<br>North Harbour, Auckland, 0751<br>New Zealand                            |
| Telephone (NZ):                   | +64 9 914 9999   |
| Fax (NZ):                         | +64 9 914 9990   |
| Emergency Telephone (NZ):         | 0800 764 766 Poisons Hotline (24 hours / 7 days)<br>National Poison Centre (New Zealand) |

## 2. HAZARDS IDENTIFICATION

|  |      |
|--|------|
| <b>GHS Classification &amp; Label Elements:</b>  |      |
| 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. |      |
| <b>Label Elements:</b>   | None |
| <b>Hazards not otherwise classified (HNOC):</b>  | None |
| <b>Safety Phrases:</b>   | 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 | 9005-65-6   | 0.1-1%     |
| Water                                    |             | 30-50%     |

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| <b>4. FIRST AID MEASURES</b> |  |
|------------------------------|--|
| 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. |

| <b>5. FIRE FIGHTING MEASURES</b> |   |
|----------------------------------|---|
| Extinguishing Media:             | Suitable extinguishing media for the surrounding fire should be used. |
| Specific Hazards:                | None  |

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

| <b>7. HANDLING AND STORAGE</b> |                                      |
|--------------------------------|--------------------------------------|
| Handling:                      | Use original container.              |
| Storage:                       | Store in cool, well ventilated area. |

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

| <b>9. PHYSICAL AND CHEMICAL PROPERTIES</b> |  |
|--|--|
| 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  |

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| Upper/Lower Flammability: | N/A  |
| Evaporation Rate:         | Not determined   |
| Viscosity:                | ≥ 55,000 cps   |

| <b>10. STABILITY AND REACTIVITY</b> |   |
|-------------------------------------|---|
| 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:            | None known  |
| Hazardous Reactions:                | None known  |

| <b>11. TOXICOLOGICAL INFORMATION</b> |  |
|--------------------------------------|--|
| Hazardous Ingredient:                | Ferric Sulfate Mixture<br>LD <sub>50</sub> (orally) MICE: 3200 mg/kg |
| Routes of Exposure:                  | Refer to Section 4 of SDS  |
| Acute & Chronic Hazards              | None known   |

| <b>12. ECOLOGICAL INFORMATION</b> |                      |
|-----------------------------------|----------------------|
| Ecotoxicity:                      | No known effects     |
| Persistence and Degradability:    | No information found |
| Bioaccumulative Potential:        | No known effects     |
| Mobility in Soil:                 | No known effects     |

| <b>13. DISPOSAL CONSIDERATIONS</b> |  |
|------------------------------------|--|
| 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. |

| <b>14. TRANSPORT INFORMATION</b>           |                |
|--|----------------|
| 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           |

| <b>15. REGULATORY INFORMATION</b> |  |
|-----------------------------------|--|
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| Precautionary Phrases: | For professional in-office use only.<br>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  |
| Note:                  | Refer to applicable international, national, and local regulations and provisions.      |

| <b>16. OTHER INFORMATION</b>    |   |
|---------------------------------|---|
| 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. |
| <b>SDS History</b>              |   |
| Date of Issue:                  | October 10 <sup>th</sup> , 2025   |
| Replaces Issue:                 | September 16 <sup>th</sup> , 2020   |
| Changes made to previous issue: | Updated issue date; Updated New Zealand importer/distributor's address; Updated proportion percentages in section 3.  |