

# Safety Data Sheet

DATE OF ISSUE: August 25, 2023

ISSUED BY PASCAL

<b>Product Name:</b>	<b>Racellet™ 2 Pellets / Racellet™ 3 Pellets</b>
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1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER	
Product Name:	Racellet™ 2 / Racellet™ 3
Product Use:	Medicated cotton pellet used for gingival retraction and local hemostasis
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	
<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 <a href="#">OSHA Hazard Communication Standard</a> , 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
Racemic Epinephrine HCl	329-63-5	Racellet 2: 0.90 – 1.40 mg/pellet Racellet 3: 0.42 – 0.68 mg/pellet

4. FIRST AID MEASURES	
Inhalation:	NA
Ingestion:	Do not induce vomiting. Give water or milk, seek medical attention.
Skin:	Flush well with soap and water for at least 15 minutes.
Eye:	Flush well with water for at least 15 minutes.
Signs and symptoms of exposure:	Nervousness, high pulse, sweating, headache.
First Aid Facilities:	Seek Medical assistance for further treatment, observation and support if necessary.

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<b>5. FIRE FIGHTING MEASURES</b>	
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.

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
Emergency Procedures:	N/A
Clean Up Procedure:	Sweep area and clean with soapy water.
Personal Precautions:	Wear gloves

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

<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:	Green cotton pellet
Odor:	None
pH:	Not determined
Vapor Pressure:	Not determined
Vapor Density:	Not determined
Relative Density:	Not determined
Boiling Point:	Not determined
Freezing / Melting Point:	Not determined
Solubility in Water:	Pellet is not water soluble; racemic epinephrine is water soluble.
Specific Gravity:	Not determined
Flash Point:	Not determined
Flammability:	Not determined
Upper/Lower Flammability:	Not determined

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Evaporation Rate:	Not determined
Viscosity:	N/A

<b>10. STABILITY AND REACTIVITY</b>	
Chemical Stability:	Stable under ordinary conditions of use and storage. Racemic epinephrine will degrade under extreme heat or light.
Reactivity:	Not determined
Conditions to Avoid:	High heat, light
Incompatible Materials:	Alkalines, Iron Salts. Contact with Ferric Sulfate solutions may form black or blue precipitate.
Hazardous Decomposition Products:	None known
Hazardous Reactions:	None known

<b>11. TOXICOLOGICAL INFORMATION</b>	
Hazardous Ingredient:	Racemic Epinephrine HCl LD <sub>50</sub> (orally) MICE: 90 mg/kg
Routes of Exposure:	Refer to Section 4 of MSDS
Acute & Chronic Hazards:	None known if used as indicated and directed

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

<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:	N/A
Australian Classification Statement (ADG):	N/A
UN Number:	N/A
Proper Shipping Name:	N/A

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Environmental Hazards:	None
Special Precautions during Transport:	None

<b>15. REGULATORY INFORMATION</b>	
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.

<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:	August 25, 2023
Replaces Issue:	October 30, 2017
Changes made to previous issue:	Updated issue date to comply with mandated five-year requirement; In section 15 updated Australia AIC requirements and added CA Prop 65 requirements.