

Safety Data Sheet

DATE OF ISSUE: September 16, 2020

ISSUED BY PASCAL

Product Name: Racellet™ 2 Pellets / Racellet™ 3 Pellets

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 Bellevue, Washington 98004
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
Importer:	Ivoclar Vivadent Ltd.
Address:	12 Omega St., Rosedale, Auckland New Zealand
Telephone:	+ 64 9 914 9999
Fax:	+ 64 9 914 9990
Further information obtainable:	Regulatory Affairs sds@ivoclarvivadent.com
Emergency telephone number:	0800 764 766 (National Poison Centre – 24 hours / 7 days)

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 <u>OSHA Hazard Communication Standard</u> , 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
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.

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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.

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:	N/A
Clean Up Procedure:	Sweep area and clean with soapy water.
Personal Precautions:	Wear gloves

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

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:	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

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Product Name:	Racellet™ 2 Pellets / Racellet™ 3 Pellets
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
Evaporation Rate:	Not determined
Viscosity:	N/A

10. STABILITY AND REACTIVITY	
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

11. TOXICOLOGICAL INFORMATION	
Hazardous Ingredient:	Racemic Epinephrine HCl LD ₅₀ (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

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

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:	N/A

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Product Name:	Racellet™ 2 Pellets / Racellet™ 3 Pellets
Australian Classification Statement (ADG):	N/A
UN Number:	N/A
Proper Shipping Name:	N/A

Environmental Hazards:	None
Special Precautions during Transport:	None

15. REGULATORY INFORMATION	
Precautionary Phrases:	For professional in-office use only. Keep out of reach of children.
Poison Schedule:	None allocated
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:	September 16, 2020
Replaces Issue:	October 30, 2017
Changes made to previous issue:	Added Ivoclar's information as importer.