

Safety Data Sheet

DATE OF ISSUE: September 16, 2020

ISSUED BY PASCAL

Product Name:	Retrax [®] Pellets
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1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER	
Product Name:	Retrax [®] Pellets
Product Use:	Medicated cotton pellet used for gingival retraction and local hemostasis
Manufacturer Name:	Pascal International, Inc.
Address:	2929 Northup Way Bellevue, Washington 98004
Telephone:	1-425-827-4694, 1-800-426-8051
Fax:	1-425-827-6893
Emergency Telephone (Infotrac):	1-800-535-5053, 1-352-323-3500
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
Aluminum Sulfate, USP	10043-01-3	2.50 ± 0.30 mg / pellet (2.20 mg to 2.80 mg)

4. FIRST AID MEASURES	
Inhalation:	N/A
Ingestion:	Do not induce vomiting. Give water or milk. Seek medical attention.
Skin:	Flush well with water for at least 15 minutes for mild skin irritation.

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Product Name:	Retrax [®] Pellets
Eye:	Flush well with water for at least 15 minutes for mild eye irritation.
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

6. ACCIDENTAL RELEASE MEASURES	
Emergency Procedures:	N/A
Clean Up Procedure:	Sweep area and clean with soapy water.
Personal Precautions:	None

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:	Orange cotton pellets
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; aluminum sulfate is highly water soluble.
Specific Gravity:	Not determined
Flash Point:	Not determined
Flammability:	Not determined

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Product Name:	Retrax [®] Pellets
Upper/Lower Flammability:	N/A
Evaporation Rate:	N/A
Viscosity:	N/A

10. STABILITY AND REACTIVITY	
Chemical Stability:	Stable under ordinary conditions of use and storage
Reactivity:	None known
Conditions to Avoid:	High Heat
Incompatible Materials:	None known
Hazardous Decomposition	None known
Hazardous Reactions:	None known

11. TOXICOLOGICAL INFORMATION	
Hazardous Ingredient:	Aluminum Sulfate LD ₅₀ (orally) MICE: 6207 mg/kg
Routes of Exposure:	Refer to Section 4 of MSDS
Acute and Chronic Hazards:	Irritating to eyes, respiratory system and skin. Ingestion may cause vomiting, diarrhea, hemolysis, kidney and liver damage. Minimal amounts normally ingested are not harmful.

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 a dangerous good; not regulated
Hazchem code:	None allocated
Australian Classification Statement (ADG):	N/A
UN Number:	N/A
Proper Shipping Name:	None
Environmental Hazards:	None
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):	All ingredients are listed
Poison Schedule:	None allocated
EPA NZ	<p>Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.</p> <p>Standard for the Uniform Scheduling of Medicines and Poisons.</p> <p>Carcinogen classification under WHS Regulation 2011, Schedule 10.</p> <p>Notification status in accordance with section 3 and current national legislation.</p> <p>HSNO Approval: HSR005743</p> <p>EPA NZ Classes of hazardous properties:</p> <p>Classification 6.1D (All) Substances that are acutely toxic</p> <p>Classification 6.1D (O)</p> <p>Classification 6.3A Substances that are irritating to the skin</p> <p>Classification 6.4A Substances that are irritating to the eye</p> <p>Classification 8.1A Substances that are corrosive to metals</p> <p>Classification 9.1B (All) Substances that are very ecotoxic in the aquatic environment</p> <p>Classification 9.1B (F) Substances that are very ecotoxic in the aquatic environment</p> <p>Classification 9.3C Substances that are harmful to terrestrial vertebrates</p>
Note:	Refer to applicable international, national, and local regulations and provisions.

16. OTHER INFORMATION

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<p>Legal Disclaimer:</p>	<p>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.</p>
<p>SDS History</p>	
<p>Date of Issue:</p>	<p>September 16, 2020</p>
<p>Replaces Issue:</p>	<p>October 30, 2017</p>
<p>Changes made to previous issue:</p>	<p>Added Ivoclar's information as importer.</p>